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4 MESSING WITH SUCCESS: HOW CMS' ATTACK ON THE PART D PROGRAM

5 WILL INCREASE COSTS AND REDUCE CHOICES FOR SENIORS

6 WEDNESDAY, FEBRUARY 26, 2014

7 House of Representatives,

8 Subcommittee on Health

9 Committee on Energy and Commerce

10 Washington, D.C.

11 The subcommittee met, pursuant to call, at 10:01 a.m.,
12 in Room 2123 of the Rayburn House Office Building, Hon. Joe
13 Pitts [Chairman of the Subcommittee] presiding.

14 Members present: Representatives Pitts, Burgess,
15 Shimkus, Murphy, Blackburn, Gingrey, Lance, Cassidy, Guthrie,
16 Griffith, Bilirakis, Ellmers, Barton, Pallone, Capps,
17 Schakowsky, Green, Barrow, Christensen, Castor, Sarbanes and

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18 Waxman (ex officio).

19 Staff present: Clay Alspach, Chief Counsel, Health;
20 Sean Bonyun, Communications Director; Matt Bravo,
21 Professional Staff Member; Karen Christian, Chief Counsel,
22 Oversight; Noelle Clemente, Press Secretary; Paul Edattel,
23 Professional Staff Member, Health; Brad Grantz, Policy
24 Coordinator, O&I; Sydne Harwick, Legislative Clerk; Sean
25 Hayes, Counsel, O&I; Robert Horne, Professional Staff Member,
26 Health; Peter Kielty, Deputy General Counsel; Chris Sarley,
27 Policy Coordinator, Environment and Economy; Heidi Stirrup,
28 Health Policy Coordinator; Josh Trent, Professional Staff
29 Member, Health; Chris Pope, Fellow, Health; Ziky Ababiya,
30 Staff Assistant; Phil Barnett, Staff Director; Eddie Garcia,
31 Professional Staff Member; Kaycee Glavich, GAO Detailee; Amy
32 Hall, Senior Professional Staff Member; Karen Lightfoot,
33 Communications Director and Senior Policy Advisor; and Karen
34 Nelson, Deputy Committee Staff Director for Health.

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|
35 Mr. {Pitts.} The subcommittee will come to order. The
36 Chair recognizes himself for an opening statement.

37 The Medicare Part B Prescription Drug Benefit is a
38 government success story. Last year, nearly 39 million
39 beneficiaries were enrolled in a Part D prescription drug
40 plan. Competition and choice have kept premiums stable. In
41 fact, in 2006, the first year the program was in effect, the
42 base beneficiary premium was \$32.20 a month. In 2014, the
43 base beneficiary premium is \$32.42; a 22 cent increase over 9
44 years, and still roughly half of what was originally
45 predicted. More than 90 percent of seniors are satisfied
46 with their Part D drug coverage because of this. African-
47 American and Hispanic seniors report even higher levels of
48 satisfaction; at 95 percent and 94 percent respectively.

49 The program has worked so well because it forces
50 prescription drug plans and providers to compete for Medicare
51 beneficiaries, putting seniors not Washington in the driver's
52 seat. Part D should be the model for future reforms to the
53 Medicare Program. Instead, in its January 6, 2014, proposed
54 rule, the Centers for Medicare and Medicaid Services, CMS,
55 proposes to dismantle the very features of the program that

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56 have made it so popular and successful. CMS has taken it
57 upon itself to interpret the non-interference clause in the
58 statute to mean that it can interfere with negotiations
59 between plans and pharmacies. Congress expressly created the
60 clause to prevent CMS from doing what it intends to do in
61 this rule, yet CMS is choosing to ignore the law.

62 The proposed rule seeks to essentially eliminate
63 preferred pharmacy networks. A 2013 Milliman Study shows
64 that preferred pharmacy networks will save taxpayers \$870
65 million this year, and anywhere from \$7.9 billion to \$9.3
66 billion over the next 10 years. CMS itself says that 96
67 percent of the Part D claims it reviewed showed seniors saved
68 money at preferred pharmacies, and nearly 25,500 seniors in
69 my congressional district have chosen Part D plans with a
70 preferred pharmacy network, yet CMS would take that away from
71 them.

72 Today, the average senior has 35 different plans to
73 choose from this year. This rule would reduce that choice to
74 2 plans. Fifty percent of the plans offered today will be
75 gone, and the healthcare that seniors like may go with it.
76 Limiting seniors' choices like this will inevitably lead to
77 higher cost. By some estimates, the restrictions on the

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78 number of plans that could be offered could cause premiums to
79 rise by 10 to 20 percent. Cost to federal government may
80 increase by \$1.2 to \$1.6 billion, according to a study by
81 Milliman.

82 How is this beneficial? I am at a loss to understand
83 why CMS has proposed these changes, and what problems with
84 the Part D Drug Benefit it is attempting to solve. I don't
85 see how any of these proposals provide tangible benefits to
86 seniors, but I do see more bureaucracy, less choice and
87 competition, and higher cost to both beneficiaries and the
88 federal government in the future if the proposed rule is
89 enacted.

90 I urge Secretary Sebelius and Administrator Tavenner to
91 rescind this rule. And I welcome our witnesses here today.
92 I look forward to their testimony.

93 [The prepared statement of Mr. Pitts follows:]

94 ***** COMMITTEE INSERT *****

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|

95 Mr. {Pitts.} Thank you, and I yield the remainder of my
96 time to the gentlelady from Tennessee, Mrs. Blackburn.

97 Mrs. {Blackburn.} Thank you, Mr. Chairman. I thank you
98 for the hearing today, and I have to agree with you, Medicare
99 Part D is very popular with seniors, and the majority of
100 beneficiaries not only participate in Part D, they express
101 satisfaction with the program, and it is definitely working
102 the way it was intended.

103 I join you in being very concerned about the rule and
104 the proposed rule. This is something that would not serve
105 groups well, certainly not my seniors in Tennessee. There
106 are over 250 groups which include patients and physicians
107 that oppose the rule, and I would like to submit a letter
108 from an organization, Center Stone. I submit that for the
109 record. They provide mental health care in Tennessee.

110 Mr. {Pitts.} Without objection, so ordered.

111 [The information follows:]

112 ***** COMMITTEE INSERT *****

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|

113 Mrs. {Blackburn.} And I thank the gentleman for
114 yielding the time, and I yield back the balance of my time.

115 [The prepared statement of Mrs. Blackburn follows:]

116 ***** COMMITTEE INSERT *****

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117 Mr. {Pitts.} The Chair thanks the gentlelady. Now
118 yields to the Ranking Member of the Subcommittee, Mr.
119 Pallone, 5 minutes for an opening statement.

120 Mr. {Pallone.} Thank you, Chairman Pitts.

121 The Centers for Medicare and Medicaid Services, CMS,
122 recently proposed program changes to the Part D Prescription
123 Drug Benefit for 2015, and I believe it is important that we
124 thoughtfully examine these changes, and the effects they will
125 have on the program and on beneficiaries.

126 Unlike my Republican colleagues' tactics towards the
127 Affordable Care Act, my initial opposition to the Part D law
128 has not stopped me from working to improve and strengthen the
129 program for seniors. In fact, the ACA took important steps
130 to address the inadequacies that first caused me concern.
131 Specifically, we closed the donut hole. So I welcome today's
132 hearing so we can learn from the Agency and other
133 stakeholders about what is working and not working in the
134 Part D Program, and, of course, how we can strengthen the
135 program to work better for seniors and taxpayers alike.

136 Truthfully, it frustrates me that the Republicans are
137 politicizing this issue using alarmists and exaggerated

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138 rhetoric to make a politically-motivated point. Given the
139 significance of the Medicare Program, I hope we can have a
140 constructive and sincere discussion today on CMS's recent
141 proposals regarding the Medicare Drug Benefit. The committee
142 has a valuable function of monitoring and looking for ways to
143 improve programs under its jurisdiction, however, let's not
144 forget that CMS also plays a role in ensuring that its
145 programs are working as effectively and efficiently as
146 possible. One way it does this is by promulgating
147 regulations to make adjustments, and respond to changes in
148 the healthcare landscape and evolving needs. Importantly,
149 part of the federal rule-making process involves making the
150 proposed program changes available for public comment, and
151 taking comments into consideration before finalizing the
152 regulation.

153 Mr. Chairman, there are many positive provisions in this
154 rule that, even if it is not perfect, I do not agree with the
155 naysayers who have called for its dismissal outright.
156 Rather, we should move forward on how best to achieve our
157 objectives for a Part D program that serves its beneficiaries
158 as best as possible. For example, the proposed rule seeks to
159 make improvements to transparency, and to reducing fraud and

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160 abuse. These are issues I think we can all agree are
161 important to continue to work on. I can also see the value
162 in offering meaningful choices for beneficiaries, rather than
163 just more choices, which create unnecessary complexity in
164 making plan choices.

165 Now, there are some policies in this proposed rule that
166 give me pause. In particular, the proposed Protected Classes
167 policy. I think everyone here should share in the
168 Administration's goal of lowering prices, but I do worry that
169 the benefits to Medicare may not outweigh the risks when it
170 comes to vulnerable patient populations.

171 So, Mr. Chairman, I just hope that today we can have
172 meaningful discussion about these policies. I look forward
173 to hearing from our witnesses about the rule, and how we can
174 continue to improve and strengthen Part D.

175 I'd like to yield now the remainder of my time to Mr.
176 Green, if he'd like.

177 [The prepared statement of Mr. Pallone follows:]

178 ***** COMMITTEE INSERT *****

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179 Mr. {Green.} Thank you. Thank you for yielding to me,
180 and I want to thank the Chairman and also the Ranking Member
181 for having the hearing today.

182 Some of us were on the committee when we drafted the
183 prescription drug plan, Medicare Part D, in 2003, and it was
184 also a very partisan issue, just like the Affordable Care
185 Act. In fact, in some of my emails over the years that said
186 that the Affordable Care Act was passed at night, I really
187 remember the vote being left open for about 6 hours, and I
188 think our vote was about 5:00 a.m. in the morning, and my
189 colleague from Illinois knows that. We--that--so even
190 Congress can work at night sometimes on both issues. And I
191 also recall that the Affordable Care Act had trouble rolling
192 out. We actually worked with our constituents to help people
193 use community college, community computers to help people
194 access it, even though I considered the plan flawed.
195 Although over the years there have been changes and a reform,
196 mainly administrationwise, and I think that is what we are
197 going to see today.

198 There is--while it is clear that Part D programs provide
199 prescription drugs for Medicare beneficiaries who previously

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200 didn't have it, there is still room to improve the program.

201 And I am--have concerns about individual provisions in the

202 proposed rule, but I support increased transparency and

203 expanded access to affordable pharmacies, and cost sharing

204 for Medicare beneficiaries.

205 And again, I thank my colleague for yielding the time,

206 and I yield back.

207 [The prepared statement of Mr. Green follows:]

208 ***** COMMITTEE INSERT *****

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209 Mr. {Pallone.} And I yield back, Mr. Chairman.

210 Mr. {Pitts.} The Chair thanks the gentleman. Now

211 recognize the Vice Chair of the Subcommittee, Dr. Burgess,

212 for 5 minutes for an opening statement.

213 Dr. {Burgess.} I thank the Chairman for the

214 recognition. Mr. Blum, welcome to our committee today, and

215 to our other witnesses, we are happy to hear from you.

216 So December of last year, the end of 2013, marked the

217 10-year anniversary of the creation of the Medicare Part D

218 Prescription Drug Benefit. Not only has Part D come in at 45

219 percent under budget, the Congressional Budget Office has

220 reduced its 10-year projections for Part D by over \$100

221 billion for each of the last 3 years. The success of Part D

222 is largely attributed to its competitive, free-market

223 structure.

224 I would remind my friend from Texas that, different from

225 the Affordable Care Act, the Part D changes were non-coercive

226 and based on free-market principles, entirely different from

227 the ACA.

228 So despite a proven track record of success, the Center

229 for Medicare and Medicaid Services has proposed to

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230 fundamentally restructure the Part D Program; restructure it
231 with a 700-page rule allowing the government to interfere in
232 private plan negotiations, restrict beneficiary choice of
233 plans, and limit incentives that lower costs for consumers.
234 Only in Washington would there be a big government solution
235 in search of a problem that simply does not exist.

236 The interference from the--by the Center for Medicare
237 and Medicaid Services is projected to eliminate almost half
238 of current Part D plans in 2015. So what effect will that
239 have? Well, it is going to drive premiums higher for nearly
240 14 million seniors, and increase costs across the entire
241 Medicare Program. Even more concerning is the proposal by
242 the Center for Medicare and Medicaid Services to eliminate
243 several of the protected classes of drugs under Part D. We
244 all remember when Dr. McClellan came to this committee, and
245 the Democrats asked some pretty incisive questions, and Dr.
246 McClellan was able to defend the Part D Program based on the
247 fact that there would be these protected classes under Part
248 D. They were designed to ensure that vulnerable populations
249 of patients have continued access to lifesaving drugs. Not
250 all drugs are interchangeable, especially in the case of
251 immunosuppressants.

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252 Without this committee getting into the pharmacology of
253 how these drugs work, if we don't understand how they work,
254 how can we change the policy so that--and not affect the
255 patient at the same time? The removal of these drugs from
256 protected class status risks the lives of current and future
257 beneficiaries, further jeopardizing transplanted organs and
258 patients' lives.

259 Yet again, the Center for Medicare and Medicaid Services
260 has proposed a policy that is penny wise and pound foolish.
261 Not only has the Program increased patient access to drug,
262 and made positive effects on the health of beneficiaries, the
263 Program has extended the solvency of the entire Medicare
264 Program, saving billions of dollars over the past 10 years.
265 So rather than continue a successful program and encourage
266 innovation, now we are faced with a rule to ruin one of the
267 only working parts of our current healthcare system, leaving
268 patients with the short end of the stick.

269 I would like to submit for the record a statement by the
270 National Kidney Foundation and the American Society of
271 Transplant Surgeons. And yield to Mr. Shimkus.

272 Mr. {Pitts.} Without objection, so ordered.

273 [The information follows:]

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275 Mr. {Shimkus.} Thank you. And I thank my colleague and
276 friend.

277 More than 250 organizations united for a common goal,
278 protecting seniors and individuals with disabilities from
279 harmful changes to Medicare Part D. And that is what your
280 proposed rule actually does is harm seniors. It gives them
281 less choices, it will project higher costs, and from an
282 Administration that cut \$716 billion out of Medicare, to
283 propose a 700-page rule on--trying to fix something that is
284 not broken, is disastrous at a time when people are paying
285 more, even in the national healthcare rollout.

286 It is safe to say when I go to my district, people pay
287 more for now their insurance and get less, and this is just
288 going to fall down to our seniors.

289 I also want to focus on the fact that Medicare D has
290 been successful. I want to focus on medical therapy
291 management issues, that that--moving that level down that
292 small is just going to hurt medical therapy management for
293 those bigger populations that actually need the care.

294 And I yield the rest of my time to Dr. Cassidy.

295 [The prepared statement of Mr. Shimkus follows:]

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296 ***** COMMITTEE INSERT *****

|

297 Dr. {Cassidy.} Thank you.

298 I am a doc, and so when I talk to constituents back home
299 about how changes by Obamacare and this Administration are
300 going to decrease their choices and increase their costs, I
301 understand the issue.

302 Medicare was cut \$716 billion to fund Obamacare, and
303 frankly, when you cut that much, it is going to--it has got
304 to give. It is going to force beneficiaries to find new
305 healthcare plans, despite the President's promise that you
306 could keep your health insurance if you like it, period.
307 Instead, they get cancellation notices.

308 Now, the Medicare cut \$300 billion, or to the Medicare
309 Advantage Program, and now I understand that--for--there is a
310 further 3.55 percent cut on top of the cumulative 6.5 percent
311 cut that the industry has already suffered. It is a very
312 popular program. If you cut funding, seniors lower--have
313 less choice and increased cost.

314 Move forward, we must preserve that and decrease those
315 costs. We need policies that help seniors, not threaten

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316 access and choice.

317 I look forward to the questioning. Thank you. I yield

318 back.

319 [The prepared statement of Dr. Cassidy follows:]

320 ***** COMMITTEE INSERT *****

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321 Mr. {Pitts.} The Chair thanks the gentleman, and seeks
322 unanimous consent to enter into the record the letter from
323 Sixty-Plus Association.

324 Without objection, so ordered.

325 [The information follows:]

326 ***** COMMITTEE INSERT *****

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327 Mr. {Pitts.} The Chair now recognizes the Ranking
328 Member of the Full Committee, Mr. Waxman, 5 minutes for an
329 opening statement.

330 Mr. {Waxman.} Thank you, Mr. Chairman.

331 Today's hearing will focus on the Medicare Part D drug
332 program.

333 When President Bush signed the Part D benefit into law,
334 Democrats had many concerns. We thought the structure of the
335 law was too confusing for beneficiaries, we thought the donut
336 hole was bad for seniors, and we felt the law did not do
337 enough to reduce drug costs, and most of us voted against it.
338 But, Mr. Chairman, we didn't find dozens of ways to sabotage
339 the program. We didn't send out massive document requests in
340 order to delay and intimidate contractors. We didn't shut
341 down the government to try to force its repeal, or vote over
342 40 times to repeal the law. Instead, we worked with the Bush
343 Administration to make sure our constituents could get the
344 benefits they deserved, and ultimately, as part of the
345 Affordable Care Act, we improved benefits, closing the Part D
346 donut hole.

347 Mr. Chairman, your constituents and the nation would be

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348 much better off if your party took a similar approach to the
349 Affordable Care Act.

350 We improved the Part D law, but there are still
351 adjustments we can make to strengthen the program for both
352 beneficiaries and taxpayers, improving transparency and
353 addressing fraud and abuse.

354 CMS recently proposed a rule that would make some of
355 these changes. I appreciate the Agency's efforts. They show
356 that the Administration continues to work to improve Medicare
357 for seniors.

358 The proposed Part D rule provisions would increase
359 transparency, and increase access to community pharmacy
360 services. Many community pharmacies have been unable to
361 participate in Part D plan's preferred networks, even if they
362 are willing to meet the plan's preferred prices. CMS
363 proposes to allow any pharmacy who can meet the plan's prices
364 to participate. This change would increase pharmacy access
365 for patients, particularly in underserved communities where
366 patients may not have access to preferred pharmacies.

367 CMS has also proposed simplifying beneficiary choices
368 under Part D. CMS and patient advocates have long noted that
369 seniors find the array of plan choices dizzying, and that

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370 plans are using the multitude of choices to segment risks and
371 maximize profit. It makes sense for both the patient and the
372 taxpayer that CMS address these matters.

373 There are other places where I would like to see the
374 Agency rethink its approach. In particular, the Six
375 Protected Classes policy. I share the Administration's goal
376 of lowering prices, and ensuring that Medicare is able to get
377 the best deal possible. CMS has correctly observed that
378 eliminating some drugs from the Protected Classes category
379 would allow Part D plans to negotiate for lower prices, but
380 it is hard to ignore the concerns of patient groups and
381 Medicare advocates that these changes will make it more
382 difficult for seniors to get the drugs they need.

383 There is a better way. Adopting our--my Part D Drug
384 Rebate Bill, the Medicare Drug Savings Act would be a much
385 sounder and beneficiary-friendly approach. This Bill would
386 allow Part D to get some discounts on drugs for low-income
387 seniors that Medicaid and private sector purchasers receive.
388 It would, according to the CBA--CBO, save over \$140 billion
389 over the next decade.

390 The Administration as correct to include this provision
391 in its new budget. It is a commonsense idea that would save

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392 taxpayers billions of dollars without affecting access to
393 Part D drugs for seniors.

394 Mr. Chairman, I am pleased that Deputy Administrator
395 John Blum is here today to explain CMS's approaches--approach
396 in the Part D rule. I look forward to discussing how we can
397 improve Part D for seniors, and reduce taxpayers' costs, and
398 yield the--back the balance of my time.

399 [The prepared statement of Mr. Waxman follows:]

400 ***** COMMITTEE INSERT *****

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|

401 Mr. {Pitts.} The Chair thanks the gentleman, and again
402 seeks unanimous consent to enter a letter to Administrator
403 Tavenner from a coalition of 250 organizations on Medicare
404 Part D.

405 Without objection, so ordered.

406 [The information follows:]

407 ***** COMMITTEE INSERT *****

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408 Mr. {Pitts.} We have on our first panel today Mr.
409 Jonathan Blum, Principle Deputy Administrator, Centers for
410 Medicare and Medicaid Services, U.S. Department of Health and
411 Human Services. Thank you for coming today. You will have 5
412 minutes to summarize your testimony. Your written testimony
413 will be placed in the record. You are recognized for 5
414 minutes for your opening statement.

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415 ^STATEMENT OF JONATHAN BLUM, PRINCIPLE DEPUTY ADMINISTRATOR,
416 CENTERS FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT
417 OF HEALTH AND HUMAN SERVICES

|

418 ^STATEMENT OF JONATHAN BLUM

419 } Mr. {Blum.} Thank you. Chairman Pitts, Ranking Member
420 Pallone, members of the committee, thank you for the
421 opportunity to discuss our thoughts on ways to improve the
422 Part D Drug Program.

423 Mr. {Pitts.} Just pull that a little closer to you, if
424 you can. Yeah, thanks.

425 Mr. {Blum.} We believe the Medicare Part D Program has
426 never been stronger. All Medicare beneficiaries have many
427 plan choices to select from, premium growth has been flat,
428 and the Affordable Care Act took strong steps to close the
429 Part D coverage gap or donut hole. By 2010, the gap will be
430 completely closed.

431 In general, Medicare beneficiaries are satisfied with
432 their drug coverage, and there is growing evidence that the
433 Part D Drug Benefit has led to some decreases in other

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434 program costs.

435 While Medicare Part D is strong, we also see many
436 vulnerabilities that can and should be addressed. This year,
437 Medicare Part D will cost more than \$70 billion, or about 12
438 percent of total program costs. According to CBO, total
439 party spending is projected to grow dramatically faster than
440 other parts of the program. These projected spending trends,
441 as well as other vulnerabilities, led us to take a
442 comprehensive review of the Program, and to propose in an
443 open and transparent way some changes to our current
444 regulations. According to our actuaries, the proposed rule
445 will reduce overall program costs and Part D premiums.

446 In addition to rapid spending growth, we see other
447 vulnerabilities in Part D. First, while we see broad
448 measures of beneficiary satisfaction, CMS receives far too
449 many complaints from beneficiaries. In 2013, the Program
450 received over 30,000 complaints from beneficiaries regarding
451 their Part D coverage. Far too high. Second, we see very
452 high rates of inappropriate prescribing. While we are very,
453 very sensitive to the concerns we have heard over changing
454 the Protected Classes designation for three drug classes, we
455 have to acknowledge the requirement for Part D plans to cover

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456 all drugs in these classes, with very little restriction, has
457 led to harmful overprescribing particularly antipsychotic
458 drugs to sedate nursing home patients. Third, the Program
459 has too much prescriber fraud. This Agency made a commitment
460 to the Homeland Security Committee to reduce this fraud.
461 This proposed rule honors that commitment. Fourth, we have
462 seen too many Part D sponsors have significant compliance
463 issues that have resulted in harm to Medicare beneficiaries.
464 Fifth, we see weak data evidence that preferred pharmacy
465 networks always leads to cost savings for beneficiaries and
466 the taxpayers. Sixth, while most beneficiaries have many
467 plan choices, the evidence suggests that beneficiaries rarely
468 change plans, even though they could reduce their out-of-
469 pocket costs by changing plans. We support private plan
470 competition in Medicare Part D, so long as beneficiaries can
471 understand their choices and make changes easily. And
472 seventh, CMS, under current regulations, cannot share
473 detailed Part D claims data with outside researchers. We
474 believe this data, if shared appropriately, can make the
475 Program even stronger.

476 Our proposed Part D rule is designated to address all
477 these vulnerabilities, and to make the benefit work better

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478 for Medicare beneficiaries. In short, we must--we believe
479 that we must celebrate Part D's success, but also take a
480 critical look at its vulnerabilities and take action where we
481 can. The status quo is hardly perfect. However, we deeply
482 respect the views of those who have stated their concerns and
483 opposition to the rule, particularly patient groups and their
484 concerns over the changes to a protected class definition.
485 CMS will listen very carefully to the views of all party
486 stakeholders and partners. We will make our final decisions
487 after carefully reviewing all stakeholders' comments.

488 Thank you. Happy to address your questions.

489 [The prepared statement of Mr. Blum follows:]

490 ***** INSERT 1*****

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|

491 Mr. {Pitts.} The Chair thanks the gentleman. And we
492 will now go to questions and answers. I will begin the
493 questioning. Recognize myself for 5 minutes for that
494 purpose.

495 Mr. Blum, nonpartisan experts are warning us that
496 millions of seniors will see higher cost and fewer choices if
497 this regulation is finalized. Seniors in my district tell me
498 how much they enjoy the Part D Program, many times when I
499 talk to them.

500 As you acknowledge in your testimony, the Medicare Drug
501 Benefit is under-budget, and 94 percent of seniors are happy
502 with it. Why would CMS propose this regulation if everyone
503 is telling us that it is going to force seniors to lose their
504 plans, decrease access and increase cost?

505 Mr. {Blum.} Well, a couple of points, Mr. Chairman. We
506 see the overall Part D Program being a tremendous success,
507 but a nonpartisan CBO projects that Part D spending in the
508 next 10 years will grow faster than the other parts of the
509 program. It is the fastest line item for the Medicare
510 Program. The entire Medicare Program, since the Affordable
511 Care Act, has dramatically been reduced, but for Part D.

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512 Part D is projected to be the fastest-growing program.

513 Now, CMS's proposed rule is a consistent path for us to
514 simplify plan choices, to reduce, you know, kind of extra
515 plans being offered by the same plan sponsors. CMS started
516 this work back in 2010. We heard the same concerns from the
517 plan industry, the PBM industry, that those changes would
518 raise premiums, decrease choices, create greater
519 dissatisfaction. That hasn't happened.

520 As you pointed out during your opening statement, the
521 Part D premium has stayed flat, while at the same time we
522 have reduced kind of extra plan choices dramatically, cut
523 them in half. And looking at the past track record, the
524 arguments that we are hearing today were similar arguments
525 that we heard back in 2010, but those arguments haven't
526 been--those arguments back in 2010 did not prove true.

527 Mr. {Pitts.} Given the fact that the President's
528 healthcare law cut \$716 billion from seniors' Medicare
529 Program, and we are already seeing how those cuts are
530 negatively impacting seniors throughout the country, why
531 should they believe that this proposed rule won't hurt them
532 even more?

533 Mr. {Blum.} Well, I think going back to the payment

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534 reductions that were passed in the Affordable Care Act, while
535 we appreciate that there is now reduced spending within the
536 Medicare Program, we see that every signs on quality have
537 increased. We see more private plans wanting to come into
538 the Program, we see premiums remain flat. The Part D premium
539 this year was negative. Part D premiums, premiums for plans,
540 have fallen, nor risen. So we appreciate the fact that we
541 are paying less today than we paid for some services before
542 the Affordable Care Act, but every quality sign that we
543 track, every quality sign that we measure, has gone up,
544 premiums have gone down, and so we believe very strongly that
545 beneficiary care, beneficiary costs have not been impacted by
546 these changes.

547 Mr. {Pitts.} The law includes a non-interference
548 clause, which prohibits the government from interfering with
549 competition, and this has helped to prevent CMS from
550 interfering with negotiations between drug plans and
551 pharmacies. Such a prohibition has helped reduce costs for
552 our seniors.

553 I and my colleagues read your regulation to violate the
554 non-interference clause. In fact, department officials have
555 weighed-in against the very interpretation included in the

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556 proposed rule. I would ask that you open the document,
557 document 1, in the document binder before you. This memo is
558 from the HHS Inspector General, and I would ask you to read
559 the highlighted portion of the document. You can go ahead
560 and read that out loud.

561 Mr. {Blum.} So this is a statement from Kerry Weems
562 back in 2008. We agree that the Act prohibits the government
563 from interfering with negotiations between PDP sponsors and
564 pharmacists, and from instituting a price structure for the
565 reimbursement of covered Part D drugs.

566 Mr. {Pitts.} Now, did you or Agency staff specifically
567 review the Inspector General's memorandum before issuing your
568 proposed rule?

569 Mr. {Blum.} I don't know. I can check. I personally
570 did not, but I think it is important for us to explain why we
571 chose to propose this change.

572 CMS, in the course of day-to-day interactions with plans
573 and pharmacies and other entities, gets drawn into individual
574 contract disputes. Plans ask us to arbitrate contract
575 disputes with pharmacies and other entities. Pharmacies ask
576 us to arbitrate disputes from Part D plans. And we agree,
577 the statute is clear; CMS shall not interfere with the price

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578 structures. What we try to do is to articulate when and will
579 not CMS interfere with these contract disputes.

580 Now, our challenges on a day-to-day basis that plans and
581 pharmacies ask us to arbitrate, and we wanted to propose a
582 clear definition, not to degrade the non-interference, but to
583 strengthen it to make sure that we are absolutely clear with
584 partners, stakeholders, when CMS won't arbitrate contract
585 disputes, but we have no intention to negotiate price
586 structures. The law is very clear. During my time on the
587 Senate Finance Committee, that I had a hand in helping to
588 draft that provision, I understand the intent, I understand
589 why that was included.

590 Mr. {Pitts.} Well, you know, I am not sure it is
591 responsible for Agency staff to issue a rule that completely
592 contradicts the written legal opinion of the HHS Inspector
593 General.

594 So with that, I'll recognize the Ranking Member, Mr.
595 Pallone, for 5 minutes for questions.

596 Mr. {Pallone.} Thank you, Mr. Chairman.

597 You know, I know you mentioned, Mr. Chairman, the
598 Medicare Advantage changes in the ACA, and as you know,
599 every--nearly every Republican in the House of

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600 Representatives voted for or supported the very same changes
601 or savings. In fact, the savings were part of the Republican
602 budgets written by the House Budget Chair, Paul Ryan, in
603 2011, 2012 and 2013, and these same policies put in place by
604 the ACA were continued in these budgets, and the majority of
605 House Republicans voted for them in each of those years.

606 But let me ask Mr. Blum. If you listen to the critics
607 of the proposed rule that you are discussing today, it sounds
608 like the end of western civilization as we know it, and the
609 refrain we keep hearing is that most beneficiaries are
610 satisfied, and costs are lower than anticipated when the
611 Program was enacted 8 years ago, therefore, we should make no
612 changes. And today's hearing is titled Messing With Success.
613 But, frankly, I believe that we should continually seek to
614 improve Medicare for beneficiaries and taxpayers. It seems
615 strange to me that people would want to block changes that
616 could improve the Program. In fact, organizations
617 representing these so-called satisfied beneficiaries that we
618 keep hearing about, such as the National Council on Aging,
619 National Committee to Preserve Social Security, and Families
620 USA, strongly support many of your proposed changes.

621 So could you comment on why CMS chose to move forward a

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622 proposal to further strengthen Part D at this time?

623 Mr. {Blum.} Well, we see the Program being tremendously
624 successful. We also see that the Program has many
625 vulnerabilities. We receive recommendations from the IG
626 frequently for us to take stronger steps to reduce prescriber
627 fraud in the Program. We see that, while the Part D premium
628 has remained stable over the past several years, that is only
629 one part of Part D's costs, and the Part D premium doesn't
630 measure the complete cost of the Program. Part D is
631 projected to spend faster than other parts of the Program,
632 dramatically faster than the Part A Program, the Part B
633 Program.

634 We feel it is our responsibility to propose changes to
635 improve the operations. We also feel that it is our
636 responsibility to do it through propose and notice comment
637 period. We want to create a conversation that--about the
638 best ways to improve the Part D Program. We respect and we
639 will carefully review the comments, concerns and the
640 criticisms, but for us to argue that the Part D Program is
641 perfect, the status quo is perfect, is contrary to what we
642 see our obligations to this committee, to the Congress, and
643 to the beneficiaries that we serve.

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644 Mr. {Pallone.} Well, I certainly agree. We have also
645 heard that the unfettered competition in the Part D Program
646 is responsible for bringing costs down below initial
647 projections, and that the CMS rule is messing, I think the
648 word is, with competition, but could you comment on what had
649 led to the lower costs in Part D? I know you have already,
650 but maybe a little more.

651 Mr. {Blum.} Well, two points I think that are important
652 for us to state on the record. If you speak to our CMS
653 actuaries and ask them what has accounted for the lower costs
654 than projected back in 2003, I believe the number 1 answer
655 would be the fact that we have much more generic prescribing
656 happening in the Part D Program, and the fact that we have
657 fewer brand-new breakthrough medications right now on market
658 than the CMS actuary, CBO, staff projected back in 2003. So
659 it is not necessarily private competition that has caused the
660 lower Part D cost trends previously, but the fact that we
661 have kind of fewer brand-name drug--drugs coming onto the
662 Program.

663 I think it is also important for this committee to
664 understand that the Part D Program is not a truly-competitive
665 model, that it is not simply that CMS pays a fixed capitated

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666 payment to Part D plans, they can negotiate said benefits as
667 best they sit fit. Medicare in many respects is a cost-based
668 program. For the low-income beneficiaries, Medicare pays
669 just about the full cost of the benefit, not based upon a fee
670 schedule, but based upon the prices Part D plans negotiate.
671 For beneficiaries that exceed certain thresholds, the
672 catastrophic limit, Medicare pays just about the full cost of
673 those drugs past that limit. So to say that Part D is
674 competitive in a pure sense doesn't meet the statutory
675 definition of the Program, and I think what our actuaries
676 tell us is that the primary reason that Part D spending has
677 been lower than projected is the fact that we have more
678 generic prescribing, due to the fact that we have fewer new
679 brand-name drugs brought to market.

680 Mr. {Pallone.} Mr. Chair--thank you. Mr. Chairman, I
681 have 4 letters--I would ask unanimous consent. I have 4
682 letters in support of the rule and the provisions that foster
683 greater transparency and competition, as well as enhance
684 beneficiary protections, from beneficiary advocacy groups,
685 including the Medicare Rights Center, Families USA,
686 Independent Specialty Pharmacy Coalition, and the National
687 Community Pharmacists Association.

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688 Mr. {Pitts.} Without objection, so ordered.

689 [The information follows:]

690 ***** COMMITTEE INSERT *****

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|

691 Mr. {Pallone.} Thank you.

692 Mr. {Pitts.} The Chair thanks the gentleman. Now

693 recognizes the Vice Chair of the Full Committee, Mrs.

694 Blackburn, 5 minutes for questions.

695 Mrs. {Blackburn.} Thank you, Mr. Chairman. Thanks, Mr.

696 Blum, for being here.

697 Avalere has said that the changes you are going to make

698 would eliminate 39 percent of all of the enhanced plans by

699 2016, and that would be 214 of the current 552 enhanced PDP's

700 to be terminated or consolidated.

701 So what would you say to the seniors in my district who

702 like the plan that they have but cannot keep it if you get

703 your way?

704 Mr. {Blum.} Well, there are a couple of things,

705 Congresswoman. First is that CMS, since 2009, has put in

706 place a strategy to reduce the number of kind of extra plans

707 that sponsors provide. We started that process back in

708 2009/2010. We heard the same--

709 Mrs. {Blackburn.} You are doing this through the rules?

710 Mr. {Blum.} Correct.

711 Mrs. {Blackburn.} Okay. Let me ask you this. Avelair

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712 also said that the regulation would impact 7.4 million of the
713 7.9 million Medicare beneficiaries who are enrolled. That is
714 94 percent. So why would you and the President support a
715 regulation which is going to disrupt 94 percent of seniors in
716 Medicare Part D who have a plan that they like, and would
717 really like to keep it but you are not going to let them do
718 that?

719 Mr. {Blum.} So I think it is important to think about
720 the history of the marketplace. Before the donut hole was
721 closed, Part D plans oftentimes offered kind of supplemental
722 benefits to fill in that donut hole. The donut hole is now
723 being closed due to the Affordable Care Act.

724 By 2020, the donut hole will be completely closed.
725 There have been very strong steps so far to close that donut
726 hole. We see--

727 Mrs. {Blackburn.} Okay--

728 Mr. {Blum.} --little opportunity for Part D plans
729 really to distinguish themselves from other plans--

730 Mrs. {Blackburn.} So you see this--

731 Mr. {Blum.} --those same sponsors offered--

732 Mrs. {Blackburn.} --as an opportunity?

733 Mr. {Blum.} We see this as a way to simplify the Part D

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734 Program, to make it much more easier to navigate. The
735 concerns that--

736 Mrs. {Blackburn.} So by limiting choice and options,
737 you see that as a simplification and a way to improve this
738 Program?

739 Mr. {Blum.} I think some of the concerns that I hear
740 oftentimes from the beneficiary communities, that there are
741 many Part D choices, too many to choose from, and we know
742 from academic literature that the more choice, more
743 confusion--

744 Mrs. {Blackburn.} So you think people are confused?

745 Mr. {Blum.} I think--

746 Mrs. {Blackburn.} That seniors are confused--

747 Mr. {Blum.} I personally hear--

748 Mrs. {Blackburn.} --and they need CMS to--

749 Mr. {Blum.} I personally hear--

750 Mrs. {Blackburn.} --simplify that?

751 Mr. {Blum.} --tremendous confusion--

752 Mrs. {Blackburn.} Okay, let me--

753 Mr. {Blum.} --from the beneficiary community.

754 Mrs. {Blackburn.} Let me ask you another question. You
755 have talked about actuaries a lot. Are you listening to

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756 actuaries or enrollees?

757 Mr. {Blum.} We listen to both beneficiaries--

758 Mrs. {Blackburn.} You are listening to both?

759 Mr. {Blum.} --and--

760 Mrs. {Blackburn.} Okay.

761 Mr. {Blum.} And to our career actuaries.

762 Mrs. {Blackburn.} Okay. Well, you know, the surveys
763 show that 95 percent of the seniors are satisfied with their
764 plan, and Part D is estimated to cost 48 percent less than
765 initially estimated by the CBO, and Milliman has projected
766 that if your new rule goes into effect, the federal
767 government will be on the hook for \$1.6 billion more than
768 expected in 2015. So where are you going to get the money?

769 Mr. {Blum.} So I think a couple of things. I think we
770 see a future for the Part D Program that is growing very
771 quickly; 10 percent per year. That is dramatically faster
772 than other parts of the program.

773 Mrs. {Blackburn.} Okay.

774 Mr. {Blum.} So to say that we shouldn't take a critical
775 look at the future, we don't agree.

776 We heard the same concerns back in 2010 that premiums
777 would skyrocket, beneficiaries would be left by their plan

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778 when CMS started to--

779 Mrs. {Blackburn.} Yeah, we heard that--

780 Mr. {Blum.} --consolidate--.

781 Mrs. {Blackburn.} --about the Affordable Care Act, and
782 that indeed is happening. I will tell you, I would--I have
783 plenty of stories I can share with you there.

784 Well, if Part D is not broken, then why do you think you
785 need to go put something in here that is going to cost more,
786 limit options, take seniors out of their plans, you know, it
787 doesn't make a whole lot of commonsense, Mr. Blum. And I
788 think that what we would like to do is see seniors who have a
789 product they like, they are satisfied, bear in mind Medicare
790 is something seniors have had money coming out of their
791 paycheck every day of their working life and going into a
792 Medicare trust fund, and they have prepaid their
793 participation in this program, and I think that CMS needs to
794 be listening to those enrollees and maybe paying less
795 attention to these actuaries that obviously are going to give
796 you--let me ask you this. What is your goal? What are you
797 trying to achieve by this? What is your outcome?

798 Mr. {Blum.} I think we have several goals. We want to
799 reduce the prescriber fraud in the Program, we want to make

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800 the benefit less confusing, more clear to our beneficiaries,
801 we want to make sure that when the Program pays the majority
802 of costs for low-income beneficiaries, that we are paying the
803 best possible rates. When we see preferred pharmacy networks
804 being created, we want to encourage innovation--

805 Mrs. {Blackburn.} Okay.

806 Mr. {Blum.} --so long as those cost savings get passed
807 on to our beneficiaries, passed on to the taxpayers.

808 Mrs. {Blackburn.} Okay.

809 Mr. {Blum.} So Part D, yes, has been tremendously
810 successful, but we do not think it is perfect, nor do we get
811 that--

812 Mrs. {Blackburn.} My time has expired. One last
813 question. Can you cite for me the statute that gives you the
814 opportunity to go in and settle these disputes between the
815 manufacturers and the pharmacies?

816 Yield back.

817 Mr. {Blum.} Sorry, is that a question or--

818 Mr. {Pitts.} Did you want to respond?

819 Mr. {Blum.} We are happy to provide our legal
820 clarification. We see that the changes to the non-
821 interference don't weaken, but they strengthen. On a day-to-

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822 day basis we are pulled into many disputes that we feel that
823 we need to provide clear rules.

824 Mr. {Pitts.} Okay. The Chair thanks the gentlelady,
825 and now recognizes the Ranking Member of the Full Committee,
826 Mr. Waxman, 5 minutes for questions.

827 Mr. {Waxman.} Thank you, Mr. Chairman.

828 Mr. Blum, there is a lot of concern about the proposed
829 rule removing two classes of drugs, antidepressant and
830 immunosuppressants, from the list of protected classes. I
831 would like to hear your rationale. I know there are cost
832 concerns, and cost concerns are always legitimate.

833 When I did my oversight work on Part D in 2007 and 2008,
834 my investigations also revealed the prices for the drugs on
835 the Protected Classes list were much higher than they should
836 have been, but I think seriously the concerns that have been
837 expressed by patients, that removing drugs from the Protected
838 Classes list will mean their Part D plans may not cover them,
839 and seniors will not be able to get the drugs they need.

840 Give us your rationale here.

841 Mr. {Blum.} Well, I think we came to this proposal with
842 difficulty, with many--with much analysis, and kind of
843 weighing the pros and cons for a proposed change, and one of

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844 the reasons why we felt comfortable to take a careful step
845 towards lifting the class definition is that the Part D
846 Program has many protections built into place; the appeal
847 system, transition policy, the very rigorous formulary review
848 that we do for Part D plans.

849 We cover drugs in about 140 drug classes, and we have 6
850 classes that are now protected, and other drug classes that
851 treat very important conditions, diabetes, hypertension,
852 congestive heart failure, don't receive this designation, yet
853 we don't hear the concerns regarding beneficiaries having
854 access to the drugs they need.

855 Mr. {Waxman.} Well, there are a lot of concerns being
856 expressed--

857 Mr. {Blum.} Sure.

858 Mr. {Waxman.} --about this, and I appreciate your
859 efforts to reduce the taxpayer cost, and I know you are
860 serious about making sure that seniors can get the drugs they
861 need, but I believe there is a better way, and I have
862 introduced to the last two Congresses the Medicare Drug
863 Savings Act that would end one of the worst giveaways that
864 was included in the original Part D Bill.

865 For people who were covered by Medicaid, before Part D,

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866 there was a rebate for these dual eligibles, and when Part D
867 was adopted, suddenly that rebate ended and the prices of
868 those drugs went up so that the Medicare Program paid a much
869 higher price. It was a sweetheart deal. It resulted in a
870 substantial drug manufacturer windfall at taxpayers' expense.

871 My Bill would reverse that windfall, adding drug a
872 manufacturer rebate so that Medicare Part D prices are no
873 higher than prices in programs like Medicaid.

874 Do you have any thoughts on this Rebate Bill?

875 Mr. {Blum.} Well, I think the President's forced
876 legislation in his last budget, the President proposed a very
877 similar change to your legislation, to enable the Part D
878 Program to receive better prices for drugs that were
879 previously paid much less when the beneficiaries received
880 their benefits through state Medical Program.

881 Mr. {Waxman.} I would not interfere in any way with any
882 of the drugs that people would get, it would just mean a huge
883 savings for those drugs, and a--restoring the price we pay
884 for those drugs that the manufacturers received prior to Part
885 D.

886 We have heard a lot of concern about Medicare
887 beneficiaries, and I know that, Mr. Chairman, your side of

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888 the aisle talks a good game when it comes to being concerned
889 about federal spending. I would like to suggest that our
890 committee look at this opportunity, take action, and pass
891 this Bill, Medicare Drug Savings Act, which would cut
892 beneficiary costs, protecting seniors, make sure they have
893 access to drugs.

894 Mr. Blum, I have heard a great deal about CMS's
895 discussion of the non-interference provisions in the proposed
896 Part D rule. Part D statutes states Secretary may not
897 interfere with the negotiations between drug manufacturers
898 and pharmacies, and PDP sponsors may not require particular
899 formulary or institute a price structure for the
900 reimbursement of covered Part D drugs.

901 So we have a witness that has gone on to suggest that
902 your rule rests on a questionable legal foundation, it
903 violates the intent of the Congress. I would like to
904 understand this proposal a little better. Does your proposal
905 rule interfere with negotiations between drug manufacturers
906 and pharmacies?

907 Mr. {Blum.} No.

908 Mr. {Waxman.} Does your rule interfere with
909 negotiations between drug manufacturers and PDP sponsors?

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910 Mr. {Blum.} No.

911 Mr. {Waxman.} Does your rule require particular
912 formulary?

913 Mr. {Blum.} No.

914 Mr. {Waxman.} Does your rule institute a particular
915 price structure?

916 Mr. {Blum.} No.

917 Mr. {Waxman.} So it would seem to me that your rule
918 does not do anything that the Part D statute prohibits you
919 from doing, yet the mere specter of the word non-interference
920 has set some industry groups ablaze.

921 Could you briefly explain what your rule does in this
922 area? My understanding is that the proposed rule merely
923 states that whatever prices are, they all have to be reported
924 consistently, is that correct?

925 Mr. {Blum.} Correct. I think we want to make sure that
926 we are clear when and won't the Agency will become involved
927 in how Part D plans operate. As I expressed earlier, we
928 often get pulled into disagreements, contract disagreements,
929 contract disputes. Our principle is to make sure that Part D
930 plans honor the requirements, that they have to have complete
931 pharmacy networks, complete pharmacy access standards, but to

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932 me and to the Agency, this change--proposed change clarifies
933 what we believe the clause should mean in operations, to us
934 that works to strengthen the requirement, not weaken it, but
935 we have no intention to interfere in the price negotiations
936 between Part D stakeholders.

937 Mr. {Waxman.} Thank you. Thank you, Mr. Chairman.

938 Mr. {Pitts.} Chair thanks the gentleman. Now recognize
939 the gentleman, Dr. Burgess, 5 minutes for questions.

940 Dr. {Burgess.} Thank you, Mr. Chairman. And, Mr. Blum,
941 thank you, and thank you for being here.

942 If I understood correctly in your comments to Chairman
943 Pitts, you said that costs are going down. You extolled some
944 of the virtues of the Part D Program, and then in the next
945 breath you said some of the fastest growth is projected to be
946 in the Medicare Part D Program.

947 It reminds me of the old line from the Marx Brothers'
948 movie; who are you going to believe, me or your own eyes? So
949 I, you know, it almost can't be both ways. One or the--

950 Mr. {Blum.} Well--

951 Dr. {Burgess.} One or the other has got to be true.

952 Mr. {Blum.} Let me clarify please. So looking back,
953 Part D has cost the taxpayers, cost beneficiaries less than

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954 what CBO and the CMS actuaries projected back in 2003. That
955 is true, and that is a great statement for us to make
956 together, and a reason to celebrate Part D success.

957 When you look at CBO's current projections for the
958 future, not the past but the future, Part D total spending,
959 not the Part--just the Part D premium but all the pieces that
960 the Program pays, the low-income subsidy, the reinsurance,
961 that is the fastest part of the Program.

962 Dr. {Burgess.} Correct. A--but you just have to ask,
963 what is that based on? So let me ask you--

964 Mr. {Blum.} Why do you--you know that question.

965 Dr. {Burgess.} Let me--well, let me ask you. When you
966 have this proposed rule that is some 700 pages, that I assume
967 that you have read and approved--

968 Mr. {Blum.} Yes.

969 Dr. {Burgess.} --is that correct?

970 Mr. {Blum.} Correct.

971 Dr. {Burgess.} Can you provide the committee with the
972 cost analysis that you did for this rule?

973 Mr. {Blum.} Sure. The--by requirement, we have to do
974 an economic estimate. This rule was significant, so per O
975 and B process, we put our estimate--

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976 Dr. {Burgess.} Have you provided that to the committee?

977 Mr. {Blum.} That is part of the rule.

978 Dr. {Burgess.} Okay. Have you provided it already or
979 is it coming?

980 Mr. {Blum.} We are happy to send a copy of the rule to
981 you.

982 Dr. {Burgess.} Let me ask you this. In that, is there
983 also going to be the delineation of the legal justifications
984 for proposing the rule?

985 Mr. {Blum.} The proposed rule went through our general
986 counsel. They cleared it. We are happy to answer any
987 questions regarding their legal views regarding the
988 regulation.

989 Dr. {Burgess.} Well, let us--and we need that. I mean
990 it is critical to our discussion.

991 On the non-interference that has come up several times
992 this morning, the non-interference policy, the cornerstone of
993 the Part D Program, under the proposed rule, CMS reinterprets
994 this part of the statute, asserting the language of the law
995 does not apply to negotiations between pharmacies and
996 prescription drug sponsors. So in my mind, there is some
997 confusion as to why, after 10 years, your Agency felt that it

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998 must now reinterpret the non-interference clause.

999 What has changed that propelled you to make this
1000 distinction?

1001 Mr. {Blum.} Well, I think we interact with our Part D
1002 plan sponsors on a day-to-day basis. We approve, we review,
1003 we have a very rigorous process--

1004 Dr. {Burgess.} Do you have evidence to which you can
1005 point and provide to this committee why--

1006 Mr. {Blum.} We are happy to do that.

1007 Dr. {Burgess.} --you have changed?

1008 Mr. {Blum.} Yes, we are happy to do that.

1009 Dr. {Burgess.} I would ask you to submit that for the
1010 record, and how do you anticipate how the Center for Medicare
1011 and Medicaid Services intervention in these negotiations to
1012 improve the program. What is your expectation of
1013 improvement, can you provide that to the committee?

1014 Mr. {Blum.} Absolutely.

1015 Dr. {Burgess.} Are you aware of the requirements within
1016 the oft-mentioned Affordable Care Act, are you aware of the
1017 requirements to keep the proprietary contract terms
1018 confidential? That is Section 3301 of the PPACA. And it
1019 seems to me it would be contrary to the policy you are

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1020 proposing in the Part D proposed rule.

1021 Mr. {Blum.} We are happy to review that section of the
1022 statute to make sure that we are consistent.

1023 Dr. {Burgess.} And again, I would--you need to do that
1024 and it needs to be detailed.

1025 Let me just ask you again about, were you or
1026 Administrator Tavenner or Secretary Sebelius, did you receive
1027 any legal memoranda, was any legal memorandum prepared for
1028 you that provided you the ability to proceed forward with
1029 this rule?

1030 Mr. {Blum.} I am not sure about legal memorandum.

1031 Dr. {Burgess.} Well, let me restate that to the
1032 proposed non-interference interpretation.

1033 Mr. {Blum.} So let me be clear. All major regulations
1034 go through rigorous review through the department. That
1035 includes our general counsel staff. The general counsel
1036 cleared the regulation, which means they believed that CMS
1037 had the authority--

1038 Dr. {Burgess.} And had you received a memorandum to
1039 that effect?

1040 Mr. {Blum.} I don't know, but I can check for you, sir.

1041 Dr. {Burgess.} We need, the committee needs that.

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1042 Let me just ask you, were there any doctors on the panel
1043 that evaluated the immunosuppressant drugs relative to the
1044 proposed protected class?

1045 Mr. {Blum.} The CMS chief medical officer for Medicare
1046 was part of the panel. And--

1047 Dr. {Burgess.} So is that--

1048 Mr. {Blum.} --by the way, he was the same chief medical
1049 officer that helped design the Protected Classes back in
1050 2005.

1051 Dr. {Burgess.} Well, was there--has there been any
1052 breakthrough or change in the science on immunosuppressant
1053 drug treatments since 2005 that many of us on the committee
1054 might have missed?

1055 Mr. {Blum.} Well, I think we recognize the very strong
1056 views of patient groups, physician groups. We understand
1057 this is a significant change.

1058 Dr. {Burgess.} Mr. Blum, I am going to run out of time.
1059 With all due respect, it is not just strong views, you give
1060 the wrong immunosuppressive, you lose the graft. This may be
1061 a graft that has been given a living donor, or someone who
1062 donated that upon their demise, but you reject a graft. That
1063 is a big deal, and it costs you at CMS a ton of money to then

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1064 put that kidney patient, graft recipient back on dialysis
1065 after they reject their graft, or worse, then pay for another
1066 transplant some point down the road. I mean that is an
1067 incredible inefficient use of funds. So it is hard for me to
1068 believe that you really have the cost benefit analysis in
1069 hand when this type of behavior is allowed to go on at CMS.

1070 Thank you, Mr. Chairman, for your indulgence. If the
1071 gentleman wishes to respond, but I will yield back.

1072 Mr. {Blum.} I pledge that the Agency will carefully
1073 review both the clinical arguments and the concern from
1074 patient classes regarding the changes to the Protected
1075 Classes. We understand this is a change. We understand that
1076 there are clinical implications, and we will take a very
1077 careful look at the comments and the thoughtful arguments
1078 coming to us during the comment process.

1079 Mr. {Pitts.} Chair thanks the gentleman. Now recognize
1080 the gentleman from Texas, Mr. Green, 5 minutes for questions.

1081 Mr. {Green.} Thank you, Mr. Chairman, and thank you,
1082 Mr. Blum, for being here.

1083 I understand that some plans have used significant
1084 incentives, for example, zero cost sharing, to steer patients
1085 to the mail-order pharmacies, and I believe patients, of

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1086 course, should be able to choose how--the pharmacy setting
1087 that best meets their needs, whether it be mail-order or
1088 bricks and mortar, however, CMS found that these incentives
1089 caused increased demand for mail-order prescriptions,
1090 sufficient to disrupt timely delivery of prescriptions to
1091 patients. In a retail setting, the beneficiary often was
1092 notified of a problem with a prescription in real time, and--
1093 or within hours, but when it happens with a mail-order, the
1094 time it takes to find, communicate and resolve the problem
1095 may delay the delivery date and resulting in gaps into the
1096 therapy.

1097 I believe that timely access to medicines are critical
1098 for patients, and I understand CMS is proposing to establish
1099 requirements for timely fulfillment of prescriptions from
1100 mail-order pharmacies, as well as for home delivery services
1101 and retail pharmacies. This would provide consistent
1102 expectations for beneficiary access to drugs.

1103 Mr. Blum, when you proposed these standards for the
1104 timely delivery, did you come up with these standards, or
1105 were these guidelines already in existence that were--that
1106 you used to develop your proposed standards?

1107 Mr. {Blum.} Well, I think we looked at common standards

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1108 for any kind of mail program. We believe strongly that we
1109 should have both pharmacy networks and mail-order options to
1110 our beneficiaries, that both should provide value to our
1111 beneficiaries and provide clear standards. We want to make
1112 the options stronger for our beneficiaries, to work better
1113 for our beneficiaries, we want to make sure that
1114 beneficiaries understand the benefits of preferred pharmacy
1115 networks, community pharmacies and mail-order pharmacies, to
1116 ensure that both the beneficiaries see clear benefits from
1117 different delivery options, but also the taxpayers. And I
1118 think more importantly, we want to make sure that plans
1119 operate with consistent standards.

1120 We receive complaints from beneficiaries regarding the
1121 timeliness, the accuracy of drugs being shipped to them by
1122 mail we think is appropriate for all plans to compete on a
1123 level playing field to ensure that they're providing
1124 consistent care and consistent delivery to our beneficiaries.

1125 Mr. {Green.} Okay. Beneficiary groups are strongly
1126 supportive in ensuring timely access to their needed
1127 medicines, whether provided by a pharmacy counter or the
1128 mail-order. Could you further elaborate on the proposal and
1129 the ruling why CMS believes this is an important beneficiary

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1130 protection to pursue?

1131 Mr. {Blum.} Well, I think we, right now, have standards
1132 for pharmacies to fulfill drugs in a timely manner. We
1133 believe that similar kind of timely standards are appropriate
1134 for mail-order pharmacies as well, and we want to make sure
1135 that beneficiaries receive timely, you know, delivery, we
1136 want to make sure that we have clear standards, but our goals
1137 simply are to provide uniformity throughout how the benefit
1138 is delivered, and to ensure that plans compete in a
1139 transparent way.

1140 Mr. {Green.} Okay. Mr. Chairman, those are my only
1141 questions, and I will be glad to yield back.

1142 Mr. {Pitts.} Chair thanks the gentleman. Now
1143 recognizes the gentleman from Illinois, Mr. Shimkus, 5
1144 minutes for questions.

1145 Mr. {Shimkus.} Thank you, Mr. Chairman. Mr. Blum, it
1146 is good to see you again. We have worked together before,
1147 and welcome.

1148 I go to schools a lot and they talk about the
1149 Constitution, and so these questions are meant just as a
1150 position of a constitutional basis of what's Article One,
1151 which is Article Two. And the basic premise, even I taught

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1152 government history, was that the Administration forces law.
1153 That is the job of the Administration. So these questions
1154 are posed based upon a real concern out there in America that
1155 this Administration does not enforce the law, or picks and
1156 chooses which pieces of the law they want to enforce.

1157 So let me begin with stating that, as you know, the
1158 statute clearly states that CMS may not interfere with
1159 negotiations, and I quote, ``between drug manufacturers and
1160 pharmacies and PDP sponsors.''

1161 I was here, as a few of us were, when Part D was passed.
1162 That was an intentional to put that in the law, to ensure
1163 that CMS would not interfere with any of these three parties.

1164 Can you tell me why CMS has chosen, based upon this
1165 proposed rule, to go against the law as Congress intended?

1166 Mr. {Blum.} Well, I think on a practical basis, and
1167 overseeing the Part D Program on a day-to-day basis, we
1168 constantly or frequently get asked to intervene in contract
1169 disputes by plans, by hospitals, by pharmacists. And so we,
1170 you know, don't necessarily always feel that we can simply
1171 say no, we are not going to interfere when beneficiary access
1172 is a concern. We have no interest to negotiate prices
1173 between Part D plans and pharmacies and drug manufacturers,

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1174 but on a day-to-day basis, particularly when a--

1175 Mr. {Shimkus.} Well, let me--and I appreciate that, but
1176 wouldn't it be a better response if you feel the need to do
1177 that, than to have someone sponsor a piece of legislation and
1178 correct the law?

1179 Mr. {Blum.} Well, I think we--

1180 Mr. {Shimkus.} I mean constitutionally. I mean just--

1181 Mr. {Blum.} Yeah--

1182 Mr. {Shimkus.} --in the real world of how we teach our
1183 kids, that would be the correct answer.

1184 Mr. {Blum.} Well, I am not a constitutional lawyer, so
1185 I can't speak to that process with authority, but what I can
1186 articulate is the day-to-day challenge of how we operate the
1187 Program, how we get drawn into individual disputes. We are
1188 open to the best ways to--

1189 Mr. {Shimkus.} Well, let me follow on because I have
1190 two more questions that just kind of follow on with this.

1191 In the original final Part D regulations published in
1192 2005, CMS separately responded to comments on its original
1193 proposed regulation as follows: As provided in Section
1194 1860D-11(i) of the Act, we cannot intervene in negotiations
1195 between pharmacies and Part D plans. And again, in the same

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1196 document, as provided in Section 1860D-11(i) of the Act, we
1197 have no authority to interfere with the negotiations between
1198 Part D plans and pharmacies, and, therefore, cannot mandate
1199 that Part D plans negotiate the same or similar reimbursement
1200 rates with all pharmacies.

1201 So if that was the ruling from CMS based upon the law,
1202 how can the Agency today say it is not unlawful--unlawfully
1203 interpreting the non-interference clause, when CMS clearly
1204 stated in 2005 that it does not have the authority to
1205 negotiate between plans and pharmacies?

1206 Mr. {Blum.} Well, I think two points, Congressman.
1207 One, we are happy to provide our legal justification to this
1208 committee to how we got to our proposal. But second, the
1209 2005 regulations were drafted at a time before CMS had
1210 experience with reviewing, negotiating and approving Part D--
1211 competing Part D plans.

1212 When I was on the Senate Finance Committee, I think the
1213 working assumption would be only a handful of the standalone
1214 Part D drug plans would choose to provide coverage. The good
1215 news is we have many, many entities wanting to provide drug
1216 coverage to our beneficiaries. We have more plans wanting to
1217 come into the program every year. And I think the

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1218 operational realities, the complexities of day-to-day
1219 negotiations and interactions with the Agency and partners
1220 created us--or caused us to take this proposal.

1221 Mr. {Shimkus.} Let me finish with this. In the
1222 preamble discussion and the final regulation issued in April
1223 2010, CMS stated the non-interference provisions in Section
1224 1860D-11(i) of the Act explicitly provides that the Secretary
1225 may not interfere with the negotiations between pharmacies
1226 and PDP sponsors, which would include payment negotiations
1227 between the party sponsors and pharmacies for MTM services.

1228 Mr. Blum, you were director of the Center for Medicare,
1229 and had operational authority over the Part D Program in
1230 2010. Why did you--why did your interpretation of non-
1231 interference change--

1232 Mr. {Blum.} Well, I think--

1233 Mr. {Shimkus.} --four years later?

1234 Mr. {Blum.} I mean I think with more experience, with
1235 more, you know--

1236 Mr. {Shimkus.} But again, that is a debate on the law.

1237 Mr. {Blum.} Well--

1238 Mr. {Shimkus.} The law is pretty clear.

1239 Mr. {Blum.} Well, we understand the concerns regarding

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1240 the legality of the provision. We are happy to provide our
1241 justification. What I can say is that the complexity to
1242 oversee this benefit has, you know, caused us to reinterpret
1243 certain--

1244 Mr. {Shimkus.} You are not tasked to reinterpret the
1245 law. You are tasked to follow the law.

1246 Thank you, Mr. Chairman. I yield back.

1247 Mr. {Pitts.} Chair thanks the gentleman. Now
1248 recognizes the gentleman, Mr. Barrow, 5 minutes for
1249 questions.

1250 Mr. {Barrow.} Thank you, Mr. Chairman. And thank you,
1251 Mr. Blum, for being here.

1252 Mr. Blum, for seniors, Medicare is kind of like home;
1253 when you have to go there, they have to take you in. When it
1254 comes to prescription drug benefits, Medicare D is like home;
1255 when you have to go there, they have to take you in. So I
1256 want to take stock of what positive has happened before we
1257 assess the cost of the benefits to seniors, to our customers,
1258 as opposed to the institutional interests that you all have.

1259 First of all, why do you think the program is costing
1260 less than it was originally projected to? What is your
1261 number one--what is the number one takeaway we get from you

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1262 as to why the Program is costing less than projected?

1263 Mr. {Blum.} Well, I think there are many reasons why
1264 the Part D Program has cost less than the 2003 projection. I
1265 think the first reason is that the Part D Program pays for
1266 many more generic drugs today than I think CBO or the CMS
1267 actuaries projected back in 2003. I think Part D private
1268 plan competition also has caused the Part D premium to--
1269 growth to stay moderate, but I think the number one reason is
1270 the fact that we have many more generic drugs provided
1271 through the Part D Program than projected back in 2003 by CBO
1272 and the CMS actuaries. But--

1273 Mr. {Barrow.} Referring to your secondary
1274 consideration, more competition than anticipated, does that
1275 also have a role in this; the fact that other--some folks are
1276 providing generics and others aren't? Isn't that--

1277 Mr. {Blum.} Well, I think there are--

1278 Mr. {Barrow.} --a little cause and effect there?

1279 Mr. {Blum.} Well, I think there are three, you know,
1280 kind of primary reasons. The first is, you know, due to the
1281 fact that we have fewer new blockbuster brand-name drugs
1282 today on market than I think what the actuaries, CBO,
1283 projected back in 2003. I think the second reason is Part D

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1284 private plan competition. Plans compete very hard for their
1285 members, which is why we don't--do not agree that Part D
1286 premiums will skyrocket due to some changes in how we oversee
1287 Part D plans. And third is, the Agency is a much more
1288 rigorous reviewer of Part D bids and benefit plans coming
1289 into CMS. CMS negotiates vigorously with Part C plans, Part
1290 D plans, but I think the number one reason that both CBO and
1291 CMS actuaries would cite why the costs are lower than
1292 projected back in 2003 is the fact that we have fewer new
1293 blockbuster brand-name drugs than was previously the case
1294 back in 2003.

1295 Mr. {Barrow.} All right, we have taken stock of how we
1296 got here, now I want to take stock of where this--how the--
1297 where you want to take us.

1298 Let us talk about the costs and the benefits of the
1299 proposed rule. I heard in response to previous questioning
1300 that your understanding--your cost benefit analysis is in the
1301 rule. I want to focus for a second on the costs and benefits
1302 to our customers, as opposed to the cost and benefits to CMS
1303 as the--the institutional interests you all have in managing
1304 the Program the way that you all think it ought to be
1305 managed.

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1306 Can you tick-off for me just what you think of the
1307 principle costs to seniors of the direction you all want to
1308 take us in? What is going to be the impact as far as they
1309 are concerned?

1310 Mr. {Blum.} Well, I think we look at costs in a--kind
1311 of multiple ways. One, we want to make sure that the
1312 premiums, Part B premiums, Part D premiums, remain--growth
1313 remains tempered. Part B premium has been flat and for the
1314 first year has, I think, come down, which is due to the
1315 changes passed by the Affordable Care Act. The Part D
1316 premium in the last several years has stayed flat. We also
1317 want to make sure the cost sharing that beneficiaries pay--

1318 Mr. {Barrow.} Well, but my point is it stayed flat
1319 without taking the direction that you all want to take us in.
1320 Do you see foresee any kind of cost impact to the customers
1321 as a result of the proposed rule?

1322 Mr. {Blum.} Well, I think we should look back at CMS
1323 changes over the past 4 or 5 years.

1324 In 2010, we required plans to offer no more than 3
1325 plans, you know, coming down from 5, 6, 7 of benefit
1326 offerings down to 3. We heard arguments from the same
1327 entities that we hear from today that premiums will

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1328 skyrocket, when, in fact, they didn't, they stayed flat. So
1329 we don't see, based upon prior experience, that, when going
1330 from 3 plans down to 2, particularly with the Part D donut
1331 hole being filled in, that we will see--

1332 Mr. {Barrow.} Well, I am asking you whether or not
1333 there have been any--there are any adverse impacts to
1334 seniors, to our customers, as a result of the proposal you
1335 all are making, and I am hearing you say none. What are the
1336 proposed benefits that you think the seniors are going to get
1337 out of the proposed changes you all want to make?

1338 Mr. {Blum.} Well, I think they will see greater
1339 clarity, they will have greater confidence that the Program
1340 is doing everything we can to reduce Provider fraud. They
1341 will--

1342 Mr. {Barrow.} That is more of an institutional interest
1343 than a customer interest.

1344 Mr. {Blum.} Well, I think our customers have an
1345 interest to make sure that the Program doesn't pay
1346 inappropriately.

1347 Mr. {Barrow.} Sure, but they want to make sure that
1348 they are going to have the full range of options they have
1349 got too, and they want to make sure they are not going to

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1350 lose out on this as--

1351 Mr. {Blum.} Well, here--

1352 Mr. {Barrow.} --in some other way.

1353 Mr. {Blum.} Well, here is the past 5 years. We have
1354 more sponsors than ever before wanting to come into the
1355 Program. For 2015, we continue to see more plan sponsors
1356 wanting to come into the Program to expand benefits,
1357 consistent with the past trends. We have heard arguments
1358 since the Affordable Care Act that the changes to the
1359 Affordable Care Act would reduce plan premiums, when, in
1360 fact--I am sorry, would raise premiums. They have come down
1361 by 14 percent.

1362 So I think we have to look at the past 5 years in order
1363 to make judgments regarding the future.

1364 Mr. {Barrow.} Mr. Chairman, thank you very much. I
1365 would like to follow up on this but my time has expired.

1366 Mr. {Pitts.} The Chair thanks the gentleman. Now
1367 recognizes the gentleman from Pennsylvania, Dr. Murphy, 5
1368 minutes for questions.

1369 Mr. {Murphy.} Thank you, Mr. Chairman.

1370 Despite the success of Medicare Part D, CMS proposed a
1371 rule last month that would threaten the health and wellbeing

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1372 of our most vulnerable seniors; those with mental illness.

1373 Now, having authored the Helping Families in Mental
1374 Health Crisis Act, which is H.R.3717, cosponsored by many
1375 members of this committee, it codifies protected class status
1376 for antidepressant and antipsychotic medications. And having
1377 written to Administrator Tavenner on this issue last month, I
1378 am deeply concerned that the Agency's proposal will have
1379 huge, unintended consequences.

1380 Now, this is not one of cost-saving or convenience, it
1381 is not about swapping generic and brand drugs. Apparently, a
1382 panel is what advised you on making these changes, and some
1383 consultant. Do you have a list of the panel members who made
1384 this decision?

1385 Mr. {Blum.} We can provide it. They were CMS career
1386 physicians and pharmacists.

1387 Mr. {Murphy.} Psychiatrists?

1388 Mr. {Blum.} I don't know, but I can check for you, sir.

1389 Mr. {Murphy.} I see. I would think that psychiatric
1390 medication, some decision would be made by a psychiatrist.

1391 So these are career people, so they work where?

1392 Mr. {Blum.} Within CMS, but I want to also clarify--

1393 Mr. {Murphy.} Are they practicing physicians?

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1394 Mr. {Blum.} I am not sure, but one thing I want to
1395 make--also clarify is that our analysis is on the Web. We
1396 proposed the change in an open way, and we understand--

1397 Mr. {Murphy.} No, I read the analysis and it does not
1398 say who did it, and it has very limited things.

1399 So let me offer you something. So is it true that, in
1400 terms of the proposed rule, there were things from the APA
1401 Practice Guidelines that said the effectiveness of
1402 antidepressant medications is generally comparable between
1403 classes and within the class of medications. You know that
1404 is what the register wrote, are you aware of that?

1405 Mr. {Blum.} Yes.

1406 Mr. {Murphy.} Okay. Is it your view that drugs covered
1407 in Medicare Part D 6 protected classes are interchangeable?

1408 Mr. {Blum.} I think--our clinical review is that some
1409 of the drugs are today and--

1410 Mr. {Murphy.} I--no, I didn't ask. That is it. Well,
1411 let me go on. Did you validate your findings with the
1412 American Psychiatric Association?

1413 Mr. {Blum.} We proposed these changes in an open way.
1414 We are going to listen very carefully to comments from all
1415 medical societies.

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1416 Mr. {Murphy.} Including the National Association on
1417 Mental Illness--

1418 Mr. {Blum.} We will--I plan--

1419 Mr. {Murphy.} --and the National Council for Behavioral
1420 Health?

1421 Mr. {Blum.} --tomorrow--we will work very carefully
1422 with both the clinical patient communities to ensure that
1423 our--

1424 Mr. {Murphy.} How about the National Institute on
1425 Mental Health?

1426 Mr. {Blum.} We are happy to meet with all stakeholders.

1427 Mr. {Murphy.} Now, I have in my hand a letter here from
1428 the American Psychiatric Association, and I want to read you
1429 a couple of quotes from this. It says we find it
1430 particularly disturbing that CMS used selective and improper
1431 references to APA Treatment Guidelines as justification for
1432 limiting coverage of its medications. The letter goes on to
1433 state that selective quoting from our guidelines and flawed
1434 clinical logic apparently led CMS to conflate the supposed
1435 interchangeability of drugs within the classes of both
1436 antidepressant and antipsychotics with overall evidence for
1437 efficacy when this is just one element of a drug's

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1438 appropriateness for an individual patient.

1439 Were you aware that CMS selectively quoted from the APA?

1440 Mr. {Blum.} Well, I think one of our principles, sir,

1441 was to make sure that we--

1442 Mr. {Murphy.} Yes or no--

1443 Mr. {Blum.} We--

1444 Mr. {Murphy.} --were you aware?

1445 Mr. {Blum.} We made--wanted to make sure that our

1446 analysis was public, detailed--

1447 Mr. {Murphy.} I see. There is a letter in front of

1448 you. You have that letter?

1449 Mr. {Blum.} Yeah.

1450 Mr. {Murphy.} There is a highlighted section.

1451 Mr. {Blum.} Sure.

1452 Mr. {Murphy.} Could you read that out loud?

1453 Mr. {Blum.} CMS also cited the APA Treatment Guidelines

1454 in support of its claim that there is a lack of unique

1455 effects for distinguishing individual drug products when

1456 initiating drug therapy, and that treatment guidelines

1457 generally do not advocate preference of one SSRI drug over

1458 another for initiation of therapy. CMS's conclusion is not

1459 supported by the evidence it cites. It misinterprets and

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1460 misrepresents APA's clinical practice guidelines multiple
1461 times as justification for limiting patient access to the
1462 necessary products.

1463 Mr. {Murphy.} Exactly. So it important. I mean you
1464 are going back then for a comment, but you didn't list them
1465 in the first place.

1466 Do you know what an SSRI is?

1467 Mr. {Blum.} I have been advised.

1468 Mr. {Murphy.} Do you know how long it takes for one to
1469 take effect?

1470 Mr. {Blum.} Not personally, but I have been advised.

1471 Mr. {Murphy.} About 2 to 4 weeks, and yet there is a
1472 standard here if it doesn't have an impact on someone's
1473 hospitalization within 7 days, it can be disregarded.

1474 Do you know the according to the National Alliance on
1475 Mental Illness, that seniors who died by suicide, 20 percent
1476 of them do it the day of their doctor's appointment, 40
1477 percent the week of their doctor's appointment, and 70
1478 percent the month of their doctor's appointment? So
1479 psychiatrists and their patients know that not all
1480 medications are created equal. Each one is in a different
1481 therapeutic, or within a therapeutic class have different

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1482 molecular makeups, different side-effects, different drug-
1483 drug interactions, they impact a person's brain in unique
1484 ways, which is why physicians and patients with serious
1485 mental illness often try different therapies until they find
1486 the right one that works.

1487 If you restrict access to these drugs, you restrict the
1488 treatment of mental illness, you impact increasing hospital
1489 stays, you raise suicide rates among a population that has an
1490 increased suicide rate once people reach 65, and you restrict
1491 and you forbid the use of life-saving drugs.

1492 On behalf of the mental health community, I urge CMS to
1493 reconsider, because senior citizens with schizophrenia,
1494 bipolar illness or depression, this is a matter of life and
1495 death. So I want to ask you, will you commit to removing
1496 this unscientific, callous and anti-medical decision that
1497 will lead to harm for seniors with mental illness?

1498 Mr. {Blum.} Sir, I will commit to making sure that our
1499 policy is right for patients.

1500 Mr. {Murphy.} Sir, you are not a physician. You are
1501 the peoples' worst fears. You have no background, no
1502 education, no training, and it sounds like the people in this
1503 panel are not practicing physicians either and not

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1504 psychiatrists. You are practicing medicine without a
1505 license. This cannot stand. For people who are at high risk
1506 for depression and suicide and mental illness, I urge you to
1507 go back and remove this rule.

1508 Thank you. I yield back.

1509 Mr. {Pitts.} Chair thanks the gentleman. Now
1510 recognize--without objection, so ordered.

1511 [The information follows:]

1512 ***** COMMITTEE INSERT *****

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|

1513 Mr. {Pitts.} The Chair now recognizes the gentlelady
1514 from Virgin Islands, Dr. Christensen, for 5 minutes for
1515 questions.

1516 Dr. {Christensen.} Thank you, Mr. Chairman, and thank
1517 you, Mr. Blum.

1518 I have a similar question to begin with. We have had
1519 many issues with CMS over N-stage renal disease patients and
1520 the regs that have been changed over the years. Were there
1521 any transplant physicians who served on the panel?

1522 Mr. {Blum.} I don't believe so, but again, CMS proposed
1523 these changes in an open, transparent way. We walked through
1524 in very detailed our analysis, and we welcome feedback, we
1525 welcome disagreement to ensure that we get the policy right.

1526 Dr. {Christensen.} Well, given the risks to this
1527 vulnerable population, which make up a large part of the CMS-
1528 covered--especially Medicare, covered population, it--
1529 doesn't--if they do not receive the appropriate
1530 immunosuppressant medication, doesn't CMS think it is
1531 important for a transplant physician who has experience
1532 treating patients with varying organ transplants to weigh in
1533 on how clinical practice guidelines should be interpreted?

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1534 Mr. {Blum.} We agree that CMS should do everything
1535 possible to make sure that patients receive the drugs
1536 prescribed to them, that meet their clinical needs. I think
1537 it is important to recognize that we pay for about 140 drug
1538 classes, and while we have 6 protected, we don't hear the
1539 concerns regarding lack of kind of patient access, but we--
1540 however, we deeply recognize and deeply appreciate the
1541 concerns from patient groups, physicians, and we pledge to
1542 make sure that we listen, we understand, and to have our
1543 final policies best serve patients.

1544 Dr. {Christensen.} And we appreciate that. My
1545 experience is that clinical guidelines are an important
1546 reference for physicians to use to identify the treatments
1547 with the strongest evidence base, but that they are indeed a
1548 guide and the decisions and immunosuppressant drug regimens
1549 and psychiatric medications must be tailored to the
1550 individual patients' needs, and this decision is best made by
1551 the transplant physician who really knows the medical history
1552 of the patient.

1553 I have a question that I also need to ask. CMS is
1554 proposing to make changes to the number of enhanced plans
1555 that can be offered by any one sponsor, and to the number of

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1556 contracts a sponsor can have in a bid region. I want to ask
1557 about this proposed requirement.

1558 I have seen one industry-sponsored study that says 7
1559 million beneficiaries will be affected, a letter by the
1560 Chairman notes that more than 8 million will be affected,
1561 another industry-sponsored study cites 14 million people who
1562 will be affected. The number seems to be growing like
1563 Pinocchio's nose. On the other hand, organizations
1564 representing Medicare beneficiaries are strongly supportive
1565 of the proposed two-plan requirement. They believe it
1566 strengthens the Program for beneficiaries, making choices
1567 more meaningful and making sure plans aren't gaming the
1568 system.

1569 So I would like to provide you with the opportunity to
1570 discuss these proposals. My first question is why did CMS
1571 believe it was important to address these issues, and
1572 rationalize the number of plans that can be offered in an
1573 area? Was the Agency seeing gaming?

1574 Mr. {Blum.} Well, I think one game that we have seen
1575 right now, or that the Program is now experiencing, is that
1576 some plan sponsors offer what they call enhanced coverage,
1577 that is actually coverage far cheaper than their basic

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1578 benefits. And that is a strategy to select healthier
1579 beneficiaries to lower-cost plans.

1580 Now, that may be good for the Program, but on the other
1581 hand, what happens is that the low-income beneficiaries who
1582 are auto-assigned to that higher-premium plan, if the Program
1583 pays the full premium cost, that costs the government, not
1584 saves the government. So we need to take a balanced look at
1585 how plan structures are being offered to ensure they best
1586 serve beneficiaries, they are not confusing, but they also
1587 lower total program costs--

1588 Dr. {Christensen.} Let me try to get a--

1589 Mr. {Blum.} --in our program.

1590 Dr. {Christensen.} --a couple--thank you for that
1591 clarification. Could you comment on how the federal
1592 government taxpayers and plans--well, I guess you did, with
1593 dual eligible beneficiaries are paying more than they should
1594 because of the way the plan sponsors are offering multiple
1595 plans in that area. Did that pretty much address that
1596 question?

1597 Mr. {Blum.} Well, I think beneficiaries--dual eligible
1598 beneficiaries pay the same copayment. They are fixed in
1599 statute, but the Medicare Program pays just about the

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1600 complete cost of those drugs, not based upon a set fee
1601 schedule, but based upon the prices negotiated by the Part D
1602 plans. We want to make sure that we are paying the right,
1603 correct, fair rates on an apples-to-apples basis with the
1604 Part D plans.

1605 Dr. {Christensen.} And some of us cited this proposal
1606 will hurt dual eligible beneficiaries in the basic plans, but
1607 I interpret it exactly oppositely. Some enhanced plans with
1608 dual eligibles are not enrolled and may be consolidated with
1609 other plans, but dual eligible will benefit from lower costs
1610 in the basic plans that they enroll in. If I could just get
1611 an answer to that. Is that correct?

1612 Mr. {Blum.} Well, I think we want to make sure that
1613 when plans provide what is called enhanced coverage, that it
1614 is more generous than their basic plan offerings. One, so
1615 beneficiaries clearly understand what it means to sign up for
1616 coverage that is enhanced, but also to make sure that when
1617 the Program is paying the complete cost, the full premium,
1618 that we are not paying more than what we should if the plan
1619 structures were more consistent.

1620 Dr. {Christensen.} Thank you, Mr. Chairman, for
1621 allowing the answer.

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1622 Mr. {Pitts.} Chair thanks the gentlelady, and now
1623 recognizes the gentleman from Virginia, Mr. Griffith, 5
1624 minutes for questions.

1625 Mr. {Griffith.} Thank you, Mr. Chairman. I appreciate
1626 that.

1627 Let me start off by saying that I am concerned when you
1628 keep saying, you know, you can provide us with the legal
1629 status memorandum. This appears to be a major controversy as
1630 to whether or not this--these changes are legal, and most of
1631 the folks up here believe that it is not legal, particularly
1632 when it is so large a change. And I will have to tell you,
1633 this is what happens when one agency goes rogue. It wasn't
1634 yours, but, you know, I dealt with the Solyndra situation, as
1635 many people up here did, and general counsel there did not
1636 give legal--good legal advice, in my opinion. They gave bad
1637 legal advice, the Agency acted on it, and I think they
1638 violated the law not once, but about 3 times. And that was
1639 my opinion after reviewing all of the documents involved, and
1640 all the opinions involved, is they got bad counsel. So I am
1641 going to ask you to get a second opinion after you provide us
1642 with what you already have from your legal counsel, I am
1643 going to ask that perhaps you look at getting a second

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1644 opinion because this is a very serious matter, and it appears
1645 that the legality is in serious question.

1646 Now, that being said, I have a little bit different
1647 tact, because last year, based on conditions in my district,
1648 I asked you all to do something, and that was to take care of
1649 our pharmacies. And I have recently had a conversation with
1650 one of my pharmacists who is willing to accept the price
1651 negotiated in the region, you know, just let me be able to
1652 provide my customers with the drug that they need, or the
1653 drugs that they need, and he has been told no. And so when
1654 you say to us today that you are getting a lot of complaints,
1655 I understand that.

1656 Now, my question is last year I wrote a letter, and I am
1657 going to write you another letter, thanking you all for
1658 taking care of the community pharmacies, and saying, hey, if
1659 you meet the price, you can do it, because I represent an
1660 anonymous district, it may not be the big mountains they have
1661 in the west, but in the east we have some pretty good
1662 mountains in southwest Virginia. And so if you don't have a
1663 preferred pharmacy, you might be in the same county, but you
1664 might not be in an area where my people can get there easily,
1665 particularly if we happen to have 20 inches of snow on the

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1666 ground, it is going to be even more difficult to travel those
1667 10, 20, 30 miles that may pile up to get to the next pharmacy
1668 that is on the list. And so I do appreciate what you all did
1669 in that regard.

1670 Question becomes whether or not you have a legal basis
1671 to do it.

1672 Now, under your theory, with what you are changing in
1673 this rule, and, of course, it is not the whole 800 or 700-
1674 and-some pages, and I do have serious questions about the
1675 rest of it, you are trying to take care of that situation,
1676 you are trying to make it so that my constituents can go to
1677 the pharmacy down the street instead of having to drive
1678 around the mountain to the next pharmacy over, isn't that
1679 correct?

1680 Mr. {Blum.} So I think a couple of things. We want to
1681 make sure that we are proposing these changes in an open and
1682 transparent way. And so one of the benefits is that going
1683 through the notice and comment process, is that we get the
1684 best legal advice, not just from our lawyers but from the
1685 Congress, from outside stakeholders.

1686 And so to your first point about getting a second
1687 opinion, that is precisely why we chose to go through the

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1688 notice and comment process.

1689 To your second question regarding the pharmacists
1690 protections, we believe that party plans should be able to
1691 offer tiered pharmacy networks. We see evidence that they do
1692 reduce costs for the Program, for beneficiaries, but we have
1693 two principles. Principle one is that beneficiaries need to
1694 benefit from that--from those tiered pharmacy networks. It
1695 can't just be the plan sponsor that benefits, but it has to
1696 benefit both the beneficiaries and the taxpayers. And we
1697 agree that tiered pharmacy networks need to be fair, not just
1698 to the plan, not to the beneficiary, but to the community
1699 pharmacists. And so we have a hard time seeing the data
1700 evidence that we are seeing today, that the evidence for cost
1701 savings is mixed, and telling community pharmacies, well,
1702 they can't participate with major party plans. We want
1703 that--those tier pharmacy networks to be fair, we want to
1704 make sure that beneficiaries see clear savings, but we agree
1705 that preferred pharmacy tools can be a good tool for the
1706 party program if structured correctly.

1707 Mr. {Griffith.} And here is the concern you are here
1708 today. Look, I think if you are fair to the beneficiaries,
1709 and I want fairness as well, if you are fair to the

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1710 beneficiaries then you are being fair to the community
1711 pharmacists because, in most cases, particularly in the rural
1712 areas, the folks know their pharmacists, they want to go to
1713 that pharmacist, and they go to somebody who is close by, and
1714 they want to make sure they don't have to drive around the
1715 mountain to get to the other side of the mountain in order to
1716 get their drugs, because it may not look like much on a map,
1717 but it is a big deal when you are having to drive that. But
1718 I have to say, you know, Mr. Shimkus was right earlier when
1719 he said the whole idea is if you don't have the authority, it
1720 doesn't much how much fairness you want, you need to bring
1721 that to us, and you need to say we need a Bill to make this
1722 fair. And if what I need to do to take care of my people is
1723 to introduce a Bill, then I will do that, but let us make
1724 sure that we don't have the Constitution being set aside
1725 because it is inconvenience.

1726 I yield back.

1727 Mr. {Pitts.} Chair thanks the gentleman. Now
1728 recognizes the gentlelady from California, Mrs. Capps, 5
1729 minutes for questions.

1730 Mrs. {Capps.} Thank you, Mr. Chairman. And Deputy
1731 Administrator Blum, thank you for your testimony today.

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1732 I believe this proposed rule has some serious problems,
1733 but it also includes some important steps forward to ensure
1734 that future CMS decisions are based on the best data
1735 available. But today's hearing shows that it is important
1736 for us to be cautious as we evaluate ways to the Program to
1737 make this program more sustainable and efficient.

1738 One area that I would like to add my voice of concern is
1739 in the proposal to eliminate some of the protected classes of
1740 prescription drug coverage. You know, I have been a public
1741 health nurse for too many years in my community, and I
1742 understand that access to the right treatment at the right
1743 time is very critical for some of our most vulnerable groups,
1744 and I have grave concern that if this rule is proposed, it
1745 would put--it could put that in jeopardy. This is especially
1746 important as many of the ailments that would lose this status
1747 are said common--morbidity affecting perhaps more--many
1748 more individuals than we might think. And while I have
1749 concerns about access for vulnerable populations due to that
1750 part of the rule, I do want to applaud the Agency for another
1751 change that will also have an important impact for improving
1752 care for patients, and that is the enhanced eligibility
1753 criteria for Part D medication therapy management, the MTM

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1754 Program.

1755 I welcome CMS's recognition of the importance of MTM
1756 that it plays in increasing medication adherence, improving
1757 healthcare outcomes, and reducing overall Program costs.
1758 Specifically, the proposed rule would lower the threshold for
1759 beneficiary eligibility, meaning that an additional 16 1/2
1760 million beneficiaries could be able to benefit from this
1761 important service.

1762 My question is, would you outline the specific benefits
1763 that you envision this expansion will deliver to
1764 beneficiaries as well as to the Part D Program, just so we
1765 get that on the record?

1766 Mr. {Blum.} Well, one of the things that we know is
1767 that there are greater opportunities to assist beneficiaries,
1768 to ensure they stay compliant, to help manage complicated
1769 polypharmacy regimes. Our team sees growing evidence that
1770 the MTM Programs can help to improve drug compliance, can
1771 lower overall costs of the Program. We agree that a well-
1772 designed Part D benefit works not only to improve patient
1773 care, but to lower total Program costs. And so our goal is
1774 to expand the availability of these programs to more
1775 beneficiaries, to ensure more beneficiaries get the benefits

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1776 of these programs.

1777 Mrs. {Capps.} Thank you. And, you know, clearly, there
1778 have been some concerns about the policies in this and other
1779 proposed rules. Maybe it is a lack of understanding, maybe
1780 it is just the complexities of the issues, but one of the
1781 main concerns we hear from supporters and opponents of
1782 changes proposed by CMS is that the data is not accurate.
1783 The proposed rule we are discussing today seems to get at
1784 some of those data discrepancies by requiring uniform
1785 standards for reporting negotiated price--drug prices across
1786 Part D sponsors, but I know that some groups are concerned
1787 that this could interfere with negotiations regarding drug
1788 prices with pharmaceutical manufacturers. It is a very
1789 complicated arena, but would you now expand on CMS's intent
1790 for this particular aspect of the proposed rule? What is the
1791 goal of this portion of the rule, and how do you think this
1792 is going to affect price negotiations, which, after all, is
1793 the bottom line?

1794 Mr. {Blum.} Well, I think a couple of things,
1795 Congresswoman. The Part D benefit is not a purely-capitated
1796 program where CMS simply pays a premium to plans, and lets
1797 the plans negotiate prices. There are other payment

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1798 mechanisms built within the Part D Program. There are risk
1799 corridors, reinsurance, catastrophic coverage, the fact that
1800 for many low-income beneficiaries, due eligibles, the Program
1801 pays just about the entire cost of the drug bill.

1802 Now, we have no interest or no policy desire to
1803 interfere with the negotiations between Part D drug plans and
1804 pharmaceutical manufacturers, but we believe that those
1805 prices should be reported, kind of consistent way, to make
1806 sure the Program is paying fairly, and if the Part D plan is
1807 benefitting from the lower negotiated price, and given the
1808 large size of the premium costs, the cost sharing, the
1809 catastrophic coverage, the reinsurance, the risk corridor,
1810 that those prices should be paid--should be reported in a
1811 consistent way to ensure those discounts not just get
1812 retained by plans, but get passed on to beneficiaries and to
1813 the taxpayers that are funding the vast majority of the
1814 Program costs.

1815 Mr. {Pitts.} Chair thanks the gentlelady. Now
1816 recognizes the gentlelady from North Carolina, Mrs. Ellmers,
1817 5 minutes for questions.

1818 Mrs. {Ellmers.} Thank you, Mr. Chairman. And thank
1819 you, Mr. Blum, for being with us today.

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1820 Mr. Blum, I think it is important that you know that
1821 over 1/2 million seniors in North Carolina will be affected
1822 by these proposed rules, and I just want to start off by
1823 stating that fact.

1824 I am a little concerned with the interpretation that
1825 you--CMS has on not interfering or arbitrating or mediating
1826 between pharmaceutical companies and manufacturers. You are
1827 basically coming in and saying we are not going to be in the
1828 middle, what we are going to do is take over and dictate. Is
1829 that not essentially what you are doing?

1830 Mr. {Blum.} I don't see any desire or attempt for us to
1831 dictate the negotiation of prices between party plans and
1832 providers, manufacturers. We believe in private plan
1833 competition, we believe in choice, but that choice that is
1834 fair to beneficiaries and fair to the taxpayer.

1835 Mrs. {Ellmers.} Okay, and you have stated that, and you
1836 are basically reiterating what I said, but essentially what
1837 you are saying is you are going to come in and control the
1838 situation as a whole, kind of as a whole umbrella effect--

1839 Mr. {Blum.} That is not what I said--

1840 Mrs. {Ellmers.} --of control.

1841 Mr. {Blum.} --Congresswoman. What I said is that we

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1842 get pulled into disagreements between plans, pharmacies,
1843 other entities. And so our view is this clarification helps
1844 to strengthen the non-interference, to describe precisely how
1845 we interpret it on a day-to-day basis, but from a day-to-day
1846 basis, CMS continuously gets pulled into disputes--

1847 Mrs. {Ellmers.} Okay. Well, let us move on. Let us
1848 move on. The CMS rule proposed that prescription drug plans
1849 are limited to offering only one standard benefit and one
1850 enhanced benefit. Is this correct?

1851 Mr. {Blum.} That is correct.

1852 Mrs. {Ellmers.} So essentially, 50 percent of the plans
1853 that are available now will be decreased and eliminated?

1854 Mr. {Blum.} I think a couple of clarifications. The
1855 first is, this is a continuation and a continuous pathway for
1856 us to reduce the number of enhanced plans. There are only 2
1857 percent of Medicare beneficiaries that are in that category
1858 of plans that could be eliminated--

1859 Mrs. {Ellmers.} But--

1860 Mr. {Blum.} --if CMS chose to finalize the proposal.
1861 When CMS moved from 5 plans down to 3 plans, we heard the
1862 same concerns, the same arguments, that premiums would
1863 skyrocket, that beneficiaries would go without coverage, they

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1864 would have to change plans. And as we have heard, you know,
1865 throughout this hearing, the Part D premium has stayed
1866 constant, has stayed flat. So we need to be concerned
1867 regarding the comments and the criticisms coming to us
1868 regarding this change, but we also have to look on the past 4
1869 or 5 years to really make a complete judgment regarding this
1870 change--proposed change.

1871 Mrs. {Ellmers.} Okay, well, there again, to your point
1872 that you are making, or you are basically justifying the
1873 reasoning behind eliminating, as you pointed, 2--only 2
1874 percent of these patients receive the benefit from what is
1875 being eliminated, correct?

1876 Mr. {Blum.} We are--I am trying to give the
1877 justification to CMS's proposal. This is still on comment,
1878 and we have--

1879 Mrs. {Ellmers.} And this is--

1880 Mr. {Blum.} --made no policy--

1881 Mrs. {Ellmers.} --from a prospective of trying to save
1882 dollars in healthcare, is that correct?

1883 Mr. {Blum.} I think our total estimates of the proposed
1884 change complete is that it is overall savings, small but
1885 overall savings, and we are also trying to make the benefit

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1886 work better for our beneficiaries.

1887 Mrs. {Ellmers.} Do you realize though that the changes
1888 that are being made to Medicare Part D will then actually
1889 increase the spending in Medicaid--Medicare Part A and Part
1890 B, because many times these patients will then be re-
1891 hospitalized, sent to the hospital for care.

1892 You cited in part of your justification at the beginning
1893 the vulnerabilities, one of which has to do with the
1894 protected classes of drugs. Nursing home patients being a
1895 large patient body that receives those medications, that is
1896 an ongoing issue. Have you ever been to a nursing home
1897 before?

1898 Mr. {Blum.} Yes, I have. And also we understand that
1899 the nursing home industry is also very concerned regarding
1900 the high rate of use, and the high degree of variability in
1901 antipsychotic use--

1902 Mrs. {Ellmers.} Okay, so would it not be more efficient
1903 than to go to the source? You cited over-prescribing of
1904 medication, wouldn't it make more sense to narrow down who it
1905 is that is prescribing drugs--over-prescribing drugs than it
1906 would be to eliminate the entire program?

1907 Mr. {Blum.} Well, I think we have--Congresswoman, we

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1908 have worked very closely with the nursing home industry--

1909 Mrs. {Ellmers.} Okay, I only have one more moment,

1910 because it is not the nursing home that prescribes the drug,

1911 it is the physicians that prescribe the drugs. So that--I

1912 want to make that clarification. In relation to the

1913 potential impact on seniors because of any willingness

1914 provider provision staff of the Energy and Commerce Committee

1915 spoke with the Office of the Actuary, who told them ``Any

1916 time you make a network wider, costs go up.'' Can you

1917 respond to that because you have just told me that this is an

1918 effort at decreasing cost?

1919 Mr. {Blum.} We agree that pharmacy networks--I agree

1920 that pharmacy networks have the potential to lower costs for

1921 the Program for beneficiaries. In our current program today,

1922 we see strong evidence that pharmacy networks do reduce

1923 costs. We also see evidence that some pharmacy networks in

1924 their current forms don't lead to cost savings for our

1925 beneficiaries and for the Program.

1926 Mrs. {Ellmers.} So you are--basically, what you are

1927 saying is a direct complete--

1928 Mr. {Blum.} What I am saying is--

1929 Mrs. {Ellmers.} --opposite opinion of the--

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1930 Mr. {Blum.} No, that is not what I am saying.

1931 Mrs. {Ellmers.} --Office of the Actuary.

1932 Mr. {Blum.} What I am saying is that we believe that
1933 pharmacy networks, if structured correctly, made clear to
1934 beneficiaries the pros and cons of preferred pharmacy
1935 networks versus not, they do reduce cost, but the data right
1936 now shows that some pharmacy networks in their current forms
1937 don't reduce costs for beneficiaries. Our goal is to make
1938 sure that pharmacy networks--preferred pharmacy networks
1939 work, and work well for beneficiaries, but also work well
1940 for--

1941 Mrs. {Ellmers.} Thank you. I--

1942 Mr. {Blum.} --and--

1943 Mrs. {Ellmers.} --have gone way over my time--

1944 Mr. {Blum.} --and for the--

1945 Mrs. {Ellmers.} --so I appreciate--

1946 Mr. {Pitts.} The Chair thanks the gentlelady. Now
1947 recognizes the gentlelady from Florida, Ms. Cassidy, 5
1948 minutes for questions.

1949 Ms. {Cassidy.} Well, I want to thank you, Chairman
1950 Pitts, for calling this Oversight hearing for Medicare Part
1951 D, and thank Mr. Blum who is here from the Center for

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1952 Medicare and Medicaid Services, and thank everyone at CMS for
1953 working to improve Medicare Part D, helping to simplify it
1954 for beneficiaries, make benefits more meaningful and cost-
1955 effective for everyone. But it has to be balanced by
1956 science, and I think that many of the many advocates for
1957 beneficiaries and those who have chronic illnesses and other
1958 sicknesses have very valid points about the Protected Class
1959 Policy.

1960 So I want to make sure everyone is aware; this is a
1961 proposed rule, this is what CMS has proposed in January,
1962 correct?

1963 Mr. {Blum.} Correct.

1964 Ms. {Cassidy.} And there is an open comment period
1965 where you can receive comments from people all across the
1966 country, whether they are medical, professionals,
1967 beneficiaries, family members, pharmacists, is that correct?

1968 Mr. {Blum.} That is correct, Congresswoman, and we
1969 pledge to meet with all stakeholders on this issue to
1970 understand comments and concerns, and this is proposed and we
1971 pledge to talk to clinicians, beneficiary groups to ensure
1972 that--

1973 Ms. {Cassidy.} And the comment period is--

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1974 Mr. {Blum.} --we get the policy right.

1975 Ms. {Cassidy.} --open until when?

1976 Mr. {Blum.} I believe March 10, March 14.

1977 Ms. {Cassidy.} Okay. Mr. Blum, many private insurance
1978 plans steer patients toward preferred pharmacy networks and
1979 mail-order pharmacies in an attempt to lower costs, but CMS
1980 has found that total drug costs were not consistently lower
1981 in preferred pharmacy networks, and, in fact, the retail
1982 pharmacies in the non-preferred network were actually
1983 offering savings to the Medicare Trust Fund through
1984 discounted generics at prices below those offered by
1985 pharmacies with preferred cost sharing.

1986 And I hope you have reviewed the research done by the
1987 National Community Pharmacist Association. The community
1988 pharmacists chose one commonly purchased prescription drug
1989 plan, and entered in the Medicare plan finder for the most
1990 frequently prescribed drugs; the generic version of Lipitor,
1991 the generic version of Plavix, Diovan and Nexium. The costs
1992 were then compared between preferred, mail-order and non-
1993 preferred pharmacies in 9 cities across the country, and
1994 according to the analysis, I think it is quite surprising, 89
1995 percent of the time preferred pharmacy costs to Medicare were

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1996 higher than those of non-preferred pharmacies, and 100
1997 percent of the time, mail-order costs to Medicare exceeded
1998 those of non-preferred pharmacies.

1999 Now, this is really counterintuitive to how you think it
2000 would work. How can Medicare be paying more for mail-order
2001 and more for drugs at preferred pharmacies? Medicare is
2002 supposed to be benefitting from competition here that will
2003 bring prices down, and it is troubling that plans are
2004 offering little to no savings in the aggregate in their
2005 preferred pharmacy pricing, particularly in mail-order for
2006 generic drugs. So instead of passing on lower costs
2007 available through economy scale of deeper discounts, a few
2008 sponsors are actually charging the Program higher prices. So
2009 preferred networks and mail-order pharmacies should save the
2010 patient and the Medicare Program money, I would think.

2011 So I would like to ask you first, is the situation I
2012 have described where mail-order and preferred pharmacies are
2013 costing Medicare more than community pharmacies, similar to
2014 what CMS found in your analysis of Part D?

2015 Mr. {Blum.} Thank you for the question.

2016 First, to clarify. The comment period for the proposed
2017 rule closes March 7. I apologize for not giving the accurate

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2018 answer.

2019 To your question regarding preferred pharmacy networks.

2020 I think the reason why CMS proposed this change was that we
2021 saw similar data results. When you look at the actual cost
2022 of the drug being paid by the Program, being paid by the
2023 beneficiary through cost sharing, there is not a consistent
2024 pattern that preferred pharmacy networks, mail-order, lead to
2025 consistent lower prices for beneficiaries, for the Program.
2026 And we want to make sure that our Part D plans have all the
2027 cost containment tools that they can use to lower costs,
2028 benefit beneficiaries, benefit taxpayers, but when the
2029 Program is permitting plans to restrict some pharmacies to
2030 not participate within their networks, we believe the
2031 principle should be that we need to demonstrate there is
2032 savings to our beneficiaries, to our taxpayers.

2033 So we embrace preferred pharmacy networks so long as
2034 they are fair to beneficiaries, they are fair to pharmacists,
2035 and they are fair to the taxpayers that fund the vast
2036 majority of the cost of the Program.

2037 Ms. {Cassidy} So you would agree that it is
2038 inconsistent with the Part D law that preferred networks
2039 would cost Medicare more money?

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2040 Mr. {Blum.} I think the intent of the Program is to
2041 ensure that Part D plans have tools to lower costs, not just
2042 the premium, but cost sharing, reinsurance payments, risk
2043 corridor payments, and that should be the principle that the
2044 Medicare Program follows.

2045 Ms. {Cassidy.} Thank you very much. I have nothing
2046 else.

2047 Mr. {Pitts.} Chair thanks the gentlelady. Now ask
2048 consent to submit for the record 3 letters; 1 from the
2049 National Association of Chain Drug Stores, 1 from the
2050 American Society of Transplantation, and 1 from the
2051 Association of Mature American Citizens.

2052 Without objection, so ordered.

2053 [The information follows:]

2054 ***** COMMITTEE INSERT *****

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|

2055 Mr. {Pitts.} Now the Chair recognizes the gentleman
2056 from New Jersey, Mr. Lance, 5 minutes for questions.

2057 Mr. {Lance.} Thank you, Mr. Chairman.

2058 Good morning to you, Mr. Blum. I will be concentrating
2059 on what I believe is an overreach by the department, and I
2060 understand when the law was written, there was a debate
2061 whether there should be negotiations involving the federal
2062 government, but as I read the law, that was clearly decided
2063 in the statutory law and I am deeply concerned at what I
2064 believe is the illegal reading of the law by the Agency.

2065 My concerns go not only to this situation but to several
2066 other situations where the Administration has unilaterally
2067 delayed the ACA. I think the Administration should have come
2068 to us in Congress with statutory change, recess appointments
2069 argued before the Supreme Court several weeks ago. I believe
2070 the Supreme Court will rule those recess appointments were
2071 unconstitutional. EPA regulation under the Clean Air Act,
2072 argued before the Supreme Court earlier this week. Now, that
2073 is not your purview, any of those matters, I understand that,
2074 but you are here this morning regarding the topic under
2075 discussion.

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2076 There is a legitimate debate in this country; whether or
2077 not there should be negotiations by HHS, I understand that,
2078 but the non-interference provision is, in my judgment,
2079 unambiguous that that is not the right or the responsibility
2080 of HHS, it does not permit negotiations between Part D
2081 sponsors and pharmacies. And as I understand what was
2082 statutorily created, Senator Grassley stated, for example,
2083 that the non-interference provision is at the heart of the
2084 Bill's structure for delivering prescription drug coverage
2085 through market competition. I think that is a good deal for
2086 consumers, rather than through price fixing by the CMS
2087 bureaucracy.

2088 In the conference report at the time the legislation
2089 became law, this is a direct quote, ``In order to promote
2090 competition, the Secretary is prohibited from interfering
2091 with the negotiations between drug manufacturers and
2092 pharmacies and PDP sponsors.'' Between drug manufacturers
2093 and pharmacies and PDP sponsors. And yet as I read what has
2094 occurred in this proposed rule, prohibits only HHS's
2095 involvement in negotiations between drug manufacturers and
2096 pharmacies, and between drug manufacturers and PDP sponsors,
2097 but under the rule, not prohibiting HHS involvement in

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2098 negotiations between pharmacies and PDP sponsors. Am I

2099 accurate in that?

2100 Mr. {Blum.} I think we have clarified how we interpret

2101 the non-interference provision of the statute. I agree that

2102 they were vitally important to the framework of the 2003

2103 legislation. During my time on the Senate Finance

2104 Committee--

2105 Mr. {Lance.} Yes.

2106 Mr. {Blum.} --I worked very closely with Senator

2107 Grassley's office--

2108 Mr. {Lance.} Yes.

2109 Mr. {Blum.} --and so I agree with--

2110 Mr. {Lance.} That is why I raised it.

2111 Mr. {Blum.} --the premise. Now, we do not believe that

2112 the Part D Program should interfere with price negotiations--

2113 Mr. {Lance.} Um-hum.

2114 Mr. {Blum.} --as I said previously, oftentimes Part D

2115 plans, pharmacists bring--try to bring the Agency into

2116 contract disputes. We felt it was important to clarify how

2117 we interpret the non-interference clause, but I am very

2118 familiar with how it was drafted, very familiar--

2119 Mr. {Lance.} Probably more familiar--

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2120 Mr. {Blum.} --with--

2121 Mr. {Lance.} --than I.

2122 Mr. {Blum.} Yeah.

2123 Mr. {Lance.} Well, thank you. Let me say, I think that
2124 the current interpretation is novel, and I think it strains
2125 statutory credulity. I think it strains the statutory text
2126 beyond reasonable limits.

2127 Now, I am an attorney, and I am familiar with the
2128 deference doctrine under Chevron, but as I read applicable
2129 law, particularly from the DC Circuit and from the Second
2130 Circuit, I think this goes well beyond any deference that
2131 would be permitted under the Chevron doctrine. And,
2132 undoubtedly, this will be litigated if the rules are
2133 finalized, and I would urge the Administration, based upon
2134 sound principles of law, to reconsider this matter, and if a
2135 change is required, as is true in so many areas, the ACA,
2136 recess appointments, EPA regulations, I urge the President of
2137 the Administration to come before Congress to seek statutory
2138 change.

2139 Thank you, Mr. Chairman.

2140 Mr. {Pitts.} The Chair thanks the gentleman. Now
2141 recognizes the gentleman from Maryland, Mr. Sarbanes, 5

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2142 minutes for questions.

2143 Mr. {Sarbanes.} Thank you, Mr. Chairman. Thank you,
2144 Mr. Blum, for being here.

2145 I think it is an important undertaking what CMS is
2146 doing. I think it is a fair expectation on the part of the
2147 taxpayers and the beneficiaries that periodically you kick
2148 the tires on the Program, even if it is working very well and
2149 we are all happy with the track record. I mean when this was
2150 first rolled out, there were problems. Democrats who were
2151 initially concerned about the Program, I think stepped up to
2152 try to improve it, and we now have a program that works well
2153 and is respected by its beneficiaries. So that doesn't mean
2154 that you don't come along every so often and try to make it
2155 better, which is what you said.

2156 So we ought to be going through this exercise, and I
2157 endorse the process that you have undertaken. The rule--the
2158 proposed rule covers a lot of different areas, as you have
2159 indicated. I share some of the concerns you have heard with
2160 respect to removing the Protected Class for certain
2161 categories of drugs, and as you know, there is a broad
2162 coalition that has expressed those concerns, and I encourage
2163 the Agency to pay careful attention to that.

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2164 In terms of the requirement to reduce the number of plan
2165 offerings, I agree with you, I think that is an important
2166 step to consider. I think you are right to point to the
2167 alarm that existed the last time you did something like this,
2168 and the track record now shows that it has been an
2169 improvement overall. And there is still potential for a lot
2170 of confusion on the part of seniors and beneficiaries when
2171 they look at the plan offerings. So as long as you are not
2172 diminishing the quality of the options that are available
2173 across the board, I think that that is a reasonable change to
2174 pursue.

2175 I share, and you have seen this on both sides of the
2176 aisle, concerns on the part of independent and community
2177 pharmacists that they are not getting the full benefit and
2178 access to some of these preferred networks and so forth, and
2179 that is clearly something that the rule is trying to address.

2180 The Medicare Program, the Part D Program, is not
2181 permitted to negotiate with drug manufacturers, correct?

2182 Mr. {Blum.} Correct.

2183 Mr. {Sarbanes.} But you reimburse plans that are
2184 themselves negotiating with those drug manufacturers.

2185 Mr. {Blum.} Correct. Part D plans negotiate the

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2186 formularies and negotiate the prices with manufacturers. It
2187 is not true that CMS simply pays a fixed premium to Part D
2188 plans. We pay many other separate payments that are based
2189 upon the actual prices being negotiated. We don't plan or
2190 don't want to interfere in those negotiations, but the 2003
2191 law that was legislated created many separate payment
2192 mechanisms that the Program pays Part D plans, and for many
2193 beneficiaries, where essentially a cost-based reimbursement,
2194 particularly for the dual-eligible beneficiaries, that
2195 receive continuity of coverage.

2196 Mr. {Sarbanes.} It is certainly fair for the Program to
2197 expect that if the plans are securing discounts, that some of
2198 that benefit would come back to the Program and to the
2199 taxpayers. If a--if the Program was not doing a
2200 reimbursement, if the patient was paying directly to a plan
2201 that originally cost \$100 for a drug, and the plan was paying
2202 the manufacturer \$75 and getting a \$25 mark-up, but then was
2203 able to go negotiate and get that for \$50, there would
2204 certainly be an outcry on the part of the consumer if none of
2205 that savings was being passed through. I think the
2206 transparency that the Program is demanding in terms of what
2207 the drug pricing is and how it works is to get to the notion

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2208 that taxpayers also have a rightful expectation that, if
2209 there are significant discounts being earned by the plans
2210 relative to the manufacturers, that some of the benefit of
2211 that ought to come back to the Program. And that doesn't--
2212 that interest on your part in transparency does not translate
2213 into interference or trying to negotiate directly with
2214 manufacturers, or anything else, that is just basic fair
2215 transparency. Is that not right?

2216 Mr. {Blum.} Correct, and we believe that competition
2217 has served the Part D Program well in the past 10 years. At
2218 the same time, we believe that prices reported to the Program
2219 for purposes of paying cost sharing assistance or other, you
2220 know, kind of payment mechanisms need to be reported in a
2221 consistent way to ensure that competition is fair, to ensure
2222 that both beneficiaries and taxpayers benefit from that
2223 competition.

2224 Mr. {Lance.} Thank you.

2225 Mr. {Pitts.} Chair thanks the gentleman. Now recognize
2226 the gentleman from Louisiana, Dr. Cassidy, 5 minutes for
2227 questions.

2228 Dr. {Cassidy.} Hi, Mr. Blum.

2229 Mr. {Blum.} How are you?

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2230 Dr. {Cassidy.} You always know your stuff, man. I
2231 don't always agree with you, but you know your stuff, so
2232 thank you.

2233 Let us just put it on the table. In your testimony, you
2234 mentioned the concerns, recent changes to the MA Program will
2235 result in lower enrollment, higher cost appear unfounded, but
2236 let us be honest, only a small fraction of the scheduled cuts
2237 have come into being, and, indeed, the cuts that were already
2238 scheduled were papered over by large grants by CMS. I would
2239 note, GAO questioned the legality of those demonstration
2240 projects. A cynic would say they were being paper over--
2241 papered over prior to the last presidential campaign, but far
2242 be it from me to accuse the Administration of politics.

2243 So given that, I mean you see no basis that these cuts
2244 going forward could have an impact on the care that patients
2245 are receiving?

2246 Mr. {Blum.} So before the Affordable Care Act was
2247 signed into law, Medicare paid on average about 13 to 14
2248 percent more than the same cost for the traditional Fee-For-
2249 Service Program. Today, we are paying roughly about 103
2250 percent of costs on average, compared to the Fee-For-Service
2251 Program. So a dramatic decrease in the total cost that the

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2252 Program paid private plans. That includes the costs to our
2253 quality bonus demonstration.

2254 During that time period of dramatically lower premiums--

2255 Dr. {Cassidy.} But going--I--not to interrupt, we have
2256 limited time, I don't mean to be rude. Going forward, there
2257 are further cuts, I think, what, I see J.P. Morgan says that
2258 payments will be cut at least 4 percent in 2015, which is
2259 more than you suggest, but nonetheless, so the cuts begin to
2260 accelerate.

2261 Mr. {Blum.} So we estimate that the proposed change
2262 that CMS put forward last week for the Medicare Advantage
2263 Plans, on average, will be roughly the same change that was
2264 finalized for 2014, the current year. For--

2265 Dr. {Cassidy.} But without the demonstration projects.

2266 Mr. {Blum.} Net, net. So, you know, apples-to-apples
2267 comparison.

2268 In 2014, we are on track to exceed our 5 percent growth
2269 projection--

2270 Dr. {Cassidy.} But let me ask you. Those cuts are in
2271 addition to the previous cuts.

2272 Mr. {Blum.} So--

2273 Dr. {Cassidy.} So you add cuts--you have more cuts, you

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2274 have more cuts in '16 and more cuts in '17, at some point the
2275 cumulative effect, that--saying 3 percent this year is not
2276 going to result in any worsening that 3 percent last year,
2277 ignores the fact that you had 3 percent last year.

2278 Mr. {Blum.} So every year, CMS phases in parts of the
2279 Affordable Care Act changes. Every year, we hear that plans
2280 will pull out, benefits will be cut--

2281 Dr. {Cassidy.} No, no. Now you are dodging the
2282 question. The fact is is that you have an accumulation of
2283 cuts. So, sure, we can speak about rhetoric and about how,
2284 you know, you give grants and somehow it doesn't happen, but
2285 there is 3 percent, there is 3 percent, and it accelerates,
2286 and to say that it doesn't--that is not going to--I mean are
2287 you really maintaining that these cuts are going to
2288 eventually have no effect?

2289 Mr. {Blum.} I think--

2290 Dr. {Cassidy.} Yes or no.

2291 Mr. {Blum.} What we are saying is our--what I believe
2292 is that the past 5 years we have seen--

2293 Dr. {Cassidy.} Never mind. That is fine. I don't mean
2294 to be rude but this is clearly a talking point. I don't mean
2295 to be rude but I am not getting a yes or no, I am sorry.

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2296 Next, one of your things is that you are going to
2297 require physicians to be enrolled in Part D in order to
2298 participate. Now, I am a doc. I get so sick of bureaucrats
2299 telling me how to run my show. There are so many things that
2300 already are looking at me. I mean physicians must be one of
2301 the most scrutinized people in terms of bureaucracy staring
2302 at them. Why are we going to kick our box from the ability
2303 to prescribe if they are not a Medicare Provider?

2304 Mr. {Blum.} Well, I think we have--I testified to the
2305 Senate Homeland Security Committee, based upon reports from
2306 the IG that found that the Program was paying for
2307 prescriptions written by prescribers that were not licensed
2308 physicians. We think it is appropriate for us to have the
2309 same standard--

2310 Dr. {Cassidy.} Now stop. If I may, there are other
2311 ways to weed out unlicensed physicians. Do we have to say,
2312 okay, you can--if you are licensed, you cannot work for a
2313 nursing home in an underserved area, you are not going to be
2314 able to work for them, because somebody without a license
2315 should be kicked out anyway.

2316 Mr. {Blum.} Well, that is the situation that we have
2317 today. That is the rules that we have today that we rely on

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2318 state pharmacy licensure, and that hasn't worked.

2319 Dr. {Cassidy.} Now, I will say that that doesn't mean
2320 that now we are going to use, as a surrogate for that not
2321 working, another set of regulations. As--speaking for my
2322 fellow physicians who are groaning under the burden of
2323 paperwork laid upon them by CMS, and thinking about getting
2324 out of the system because they are so sick of it, this
2325 threatens a senior's access to physician care because CMS
2326 doesn't understand that one more piece of paperwork is just
2327 enough to make me retire to Florida.

2328 Mr. {Blum.} Well, we understand the burdens, but we
2329 also--

2330 Dr. {Cassidy.} If you do, you are not operationally
2331 understanding it.

2332 Mr. {Blum.} Well, we--our principle is to make sure
2333 that prescribers who are writing scripts pay for the Part D
2334 Program, are licensed--

2335 Dr. {Cassidy.} I don't see the rationale for that
2336 beyond you don't think other laws are being implemented,
2337 being enforced. It seems better to enforce those other laws
2338 than add on more regulation.

2339 Mr. {Blum.} Well, those are state laws, and I think we

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2340 feel that we have a responsibility to ensure that the
2341 taxpayers that front the vast majority of costs to the Part D
2342 Program are paying for prescriptions that are written by
2343 legitimate physicians.

2344 Dr. {Cassidy.} With that defense of further
2345 centralization of healthcare and to the federal government, I
2346 yield back.

2347 Mr. {Pitts.} Chair thanks the gentleman. Now recognize
2348 the gentleman from Kentucky, Mr. Guthrie, 5 minutes for
2349 questions.

2350 Mr. {Guthrie.} Thank you, Mr. Blum. Thank you for
2351 coming. I appreciate that.

2352 I just want to first go back to what--I think are
2353 questions that Mr. Shimkus and you had. If I heard
2354 correctly, which I think I did because I wrote it down, he
2355 quoted a 2010 position that CMS had that would not have
2356 allowed this rule to go forward, and then you said, and I
2357 quote, ``reinterpreted the law'' to allow this rule to go
2358 forward. You also said that you understand the legal
2359 concerns that we have, not in that exchange, but you
2360 understand the legal concerns that we have, which I would say
2361 you understand that, the basis is quite questionable or else

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2362 you wouldn't understand our concerns if you didn't understand
2363 how we could question that. And you say that you have been
2364 pulled in by other groups to get involved in negotiations,
2365 and you had to come up with this rule because other groups
2366 want you to be involved. And I hear from people all the time
2367 in my district; veterans, other things that they are in bad
2368 situations, and I just have to say to them I wish I could
2369 help you, but the law is the law, and it is my job to change
2370 the law and fix the law to help you in that situation, but I
2371 can't just go reinterpret the law. And that is what you
2372 said. And I think all of my colleagues, whether Republican
2373 or Democrat, House or Senate, should be really concerned with
2374 what you said today; that there could be a position of CMS,
2375 you want to do something different so you go back and
2376 reinterpret the law on a questionable basis. Or I think
2377 that--I just want to put out this--what was said, and I will
2378 give you a chance to respond to that if you want to do so, or
2379 I can go into my questions.

2380 Mr. {Blum.} Well, I think a couple of things. As I
2381 said during my opening statement, the Part D Program has many
2382 vulnerabilities, and we did a comprehensive review based upon
2383 the policy concerns that come to us from members of Congress,

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2384 stakeholders, partners, based upon our own operational
2385 experience. We chose to propose changes, to talk about our
2386 principles, to testify here today to discuss our concerns, to
2387 discuss the vulnerabilities that we see.

2388 Mr. {Guthrie.} Well, did you have to reinterpret the
2389 law to go forward with this?

2390 Mr. {Blum.} We want to invite comment, we want to
2391 invite conversation, that we don't believe the status quo for
2392 the Part D Program is perfect. There are vulnerabilities.
2393 We have to accept that. We have to accept the Program is
2394 spending \$70 billion, the fastest projected--

2395 Mr. {Guthrie.} Well, let me--

2396 Mr. {Blum.} --program--

2397 Mr. {Guthrie.} --just--I only have a--I want to get to
2398 the question, but if you have a--if all that is true, and if
2399 we accept all that, but that doesn't mean you can just do it
2400 without the legislative--

2401 Mr. {Blum.} And that is precisely what--

2402 Mr. {Guthrie.} --authority.

2403 Mr. {Blum.} That is precisely why we go through notice
2404 and comment period. We want to invite a perspective, we
2405 wanted to testify before this committee to explain our

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2406 rationale, to hear disagreement.

2407 Mr. {Guthrie.} But to the legal side. I am not just
2408 saying whether the--

2409 Mr. {Blum.} Well--

2410 Mr. {Guthrie.} --rules are correct or not or--

2411 Mr. {Blum.} --during the comment process, many
2412 stakeholders submit legal opinions, law firms submit comments
2413 to us to tell us whether we are right or we are wrong.

2414 Mr. {Guthrie.} Well, I don't--but you had to
2415 reinterpret the law to get to where you were, that was your
2416 quote.

2417 Mr. {Blum.} I would call it a clarification, sir.

2418 Mr. {Guthrie.} Okay. Well, you--okay, you said--one
2419 complaint I don't hear from my constituents is Medicare Part
2420 D. I just don't hear from them on Medicare Part D as a
2421 problem moving forward. And you did say in your opening
2422 statement--

2423 Mr. {Blum.} I would invite you to look at the
2424 complaint--

2425 Mr. {Guthrie.} I am going to look to your complaints
2426 and see, but I don't--when I go to town hall meetings, nobody
2427 stands up and says I don't like my drug plan. But--so one of

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2428 the things you said, you support competition as long as
2429 seniors understand. And, you know, that--I imagine going
2430 into a superstore and saying here is the aisle limited
2431 choices for people that are 65 and older, and here is the
2432 rest of the superstore for everybody else. And, you know, it
2433 just says, you know, they do understand and it is--the
2434 Milliman report says up to 15 percent of Part D plan choices
2435 may be eliminated or materially changed during 2015 or 2016,
2436 based on provisions in the rules. So some of my constituents
2437 will have plans that they chose, plans that they like, and if
2438 they like what they have, they can keep it, as we have heard,
2439 and I know that when constituents under the ACA were--plans
2440 were changed, and people were just saying, well, they were
2441 paying for something they shouldn't have paid for because it
2442 wasn't worthy insurance. I have heard that even in this
2443 committee. And, obviously--so that is just assuming people
2444 don't understand what they are buying. And I don't think
2445 that is the case. I think people are far more sophisticated
2446 and smarter than maybe what those kinds of comments give them
2447 credit for.

2448 And so what do I tell my constituents if they can't get
2449 plans because they are limited? You said it is only 2

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2450 percent, but that is 2 percent.

2451 Mr. {Blum.} Well, I think a couple of things. One is
2452 we want to make sure that we are incorporating into our final
2453 policies the views from the beneficiary communities,
2454 beneficiary stakeholders. What we hear from the beneficiary
2455 community is that the benefit is confusing. We hear from--or
2456 we see from the academic literature that beneficiaries would
2457 have the opportunity to reduce their out-of-pocket costs
2458 dramatically by changing plans. We want beneficiaries each
2459 year to take a critical look at their benefit offerings,
2460 because we know that many beneficiaries will be able to save,
2461 reduce their out-of-pocket costs. That is why we have
2462 private plan choices. We want competition, we want
2463 beneficiaries to evaluate and be able to understand the
2464 benefits for different plan options, but we know that most
2465 beneficiaries year-to-year don't change plans, even though
2466 they could benefit dramatically by changing plans.

2467 Part of the reason that we hear from the beneficiary
2468 community, and again, we invite this public conversation, is
2469 the benefit is confusing. We see plans cherry-picking the
2470 healthiest beneficiaries, raising costs for the rest of the
2471 program. But we will respectfully review and carefully

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2472 review comments sent to us to make sure that we are fostering
2473 competition, but in a way that helps beneficiaries choose the
2474 best possible plan, but also make sure the taxpayers don't
2475 overspend. I would hope the Congress would want us to manage
2476 the Part D budget in the most prudent way.

2477 Mr. {Guthrie.} Well, thanks. I do appreciate you
2478 coming today. Appreciate it, and I yield back.

2479 Mr. {Pitts.} Chair thanks the gentleman. Now
2480 recognizes the gentleman from Georgia, Dr. Gingrey, 5 minutes
2481 for questions.

2482 Dr. {Gingrey.} Mr. Blum, you have been with CMS since
2483 2009, is that correct?

2484 Mr. {Blum.} Correct.

2485 Dr. {Gingrey.} You have been in this current position,
2486 number 2 guy, for, what, about a year?

2487 Mr. {Blum.} Roughly speaking, yes.

2488 Dr. {Gingrey.} Yeah. And I certainly can understand a
2489 new coach coming in, wanting to do something kind of drastic,
2490 but quite honestly--and I commend you on the transparency
2491 aspect of this proposed rule, but I think the rule is
2492 boneheaded. In fact, Bill O'Reilly would probably call it
2493 pinheaded.

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2494 I would expect, since you have been around since 2009,
2495 that you know on, let us say, a 5-year average, the last 5
2496 years, how many participants in Medicare Part D, the
2497 prescription drug plan, have reached the donut hole, what
2498 percentage on average over the past 5 years?

2499 Mr. {Blum.} I don't have the numbers in my head, but
2500 what is true is many fewer beneficiaries are hitting the
2501 donut hole because it is being closed.

2502 Dr. {Gingrey.} Yeah, but I suspect that number is
2503 pretty low. I am surprised you don't have that. Maybe
2504 somebody behind you could whisper in your ear--

2505 Mr. {Blum.} We would be happy--

2506 Dr. {Gingrey.} --and tell you--

2507 Mr. {Blum.} But I believe the numbers are roughly year-
2508 to-year--

2509 Dr. {Gingrey.} Well--

2510 Mr. {Blum.} --and it changes year-to-year, roughly 3 to
2511 4 million Medicare beneficiaries hit the donut hole--

2512 Dr. {Gingrey.} Yeah. Yeah

2513 Mr. {Blum.} --each year. However, but--

2514 Dr. {Gingrey.} I would suggest that, you know, you are
2515 trying to kill a gnat by torching a village. You are trying

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2516 to fix things that are not broken, and to do it, maybe the
2517 optics of closing the donut hole look great. And so you have
2518 to go back and say, well, we are going to look at these
2519 Protected Classes, and we are going to do something about
2520 that and we are going to save money so we can close the donut
2521 hole. And look, listen to these 6 drug classes.
2522 Antineoplastics, that is cancer, ladies and gentlemen.
2523 Anticonvulsants. Maybe we ought to add marijuana to that.
2524 Antiretrovirals, that is AIDS drugs. Antipsychotics.
2525 Antidepressants. Anti-immunosuppressants. These are people
2526 who have had transplants--renal transplants, and if they
2527 don't get the drugs necessary within 3 to 5 years--they can't
2528 pay for them, and all of a sudden they reject these
2529 transplants.

2530 I just, you know, I wish I could tell you that I was
2531 shocked at the egregiousness of this proposed rule, and that
2532 this was all just a mistake, but that would be too kind.

2533 At this point, we must recognize the pattern of this
2534 Administration attacking any healthcare program that empowers
2535 a free market, no matter the pain it causes beneficiaries. I
2536 personally, as a physician, find it reprehensible that the
2537 Administration is so against any market-based system, that

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2538 they are willing to once again harm seniors to serve the
2539 purpose. My colleague from Maryland said, you know, every
2540 now and then you have to kick the tires to see if a program
2541 is working. Well, on the Affordable Care Act, you--every
2542 time you kick the tires, your foot goes through the sidewall.
2543 So maybe you are a little reluctant, so you kick the tires of
2544 a good program and your foot comes bouncing right back in
2545 your face. And that is what is going on here. And let us be
2546 clear, this proposed rule will destroy the Part D Program as
2547 we know it. It will limit our seniors' coverage options, and
2548 it will force higher premiums, unwarranted changes to a
2549 program where beneficiaries are overwhelmingly satisfied. It
2550 just doesn't make sense.

2551 Now, Mr. Blum, even as I disagree with the contents of
2552 the rule, I also question whether CMS, you guys, even have
2553 the legal authority to reinterpret the clear Congressional
2554 intent in the Medicare Modernization Act of 2003. I was
2555 here. I was here when that was passed. The Energy and
2556 Commerce majority staff requested that CRS review the
2557 legality of your actions, and we requested a memo in
2558 response. The memo cites, and I will just give you a little
2559 bit of it because I am running out of time, a Supreme Court

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2560 decision that interpreted a statute, a court should always
2561 turn first to one cardinal cannon before all others; that a
2562 legislature says in a statute what it means, and it means in
2563 the statute what it says.

2564 Mr. Blum, Congress has opined on this. Why does CMS
2565 feel the need to act at all when the law is crystal clear on
2566 this issue?

2567 Mr. {Blum.} Well, I haven't seen the CRS reports. I
2568 would welcome having a chance to look at it.

2569 Dr. {Gingrey.} Well, Mr. Chairman, I request unanimous
2570 consent that we make this report from the Congressional
2571 Research Service on the proposed interpretation of the non-
2572 interference provision under Medicare Part D as part of a
2573 permanent record. And I will come back to the--

2574 Mr. {Pitts.} Without objection, so ordered.

2575 [The information follows:]

2576 ***** COMMITTEE INSERT *****

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2577 Dr. {Gingrey.} Let me just conclude. I am urging you,
2578 Mr. Blum, to withdraw this rule, and I personally, as a
2579 member of this committee, am prepared, and I will also urge
2580 our leadership, fight with every tool available to repeal
2581 this rule legislatively if you guys do not heed the wishes of
2582 our seniors and the American people.

2583 I have gone over my time, and, of course, I yield back,
2584 Mr. Chairman.

2585 Mr. {Pitts.} Chair thanks the gentleman. And I would
2586 like to ask the staff to provide a copy to the minority
2587 please. Chair now recognizes the gentleman from Florida, Mr.
2588 Bilirakis, 5 minutes for questions.

2589 Mr. {Bilirakis.} Thank you, Mr. Chairman. I appreciate
2590 it very much.

2591 And again, I represent over 100,000 seniors in the Tampa
2592 Bay area, and they seem to be very pleased with Medicare Part
2593 D, and I am along with Dr. Gingrey, if it isn't broke, don't
2594 fix it.

2595 Mr. Blum, specifically, I am concerned about CMS's
2596 reinterpretation of the non-interference clause of the
2597 Medicare Part D statute. It was clearly written so that CMS

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2598 would not interfere with the negotiations between drug
2599 manufacturers, pharmacies and Part D sponsors.

2600 You may or may not know that I am in a unique position
2601 here, since my father, Congressman Mike Bilirakis, was the
2602 Chairman of the Subcommittee, and again, he remembers the
2603 intent of the law as written by him and his colleagues, and
2604 it was not to allow CMS to interfere in any of these
2605 negotiations. And I was in the legislature at the time in
2606 2003, and I followed this as well, and that was my
2607 interpretation of the law; that we--the intent was for CMS
2608 not to interfere, but not to allow CMS to interfere again in
2609 the negotiations.

2610 You should know that, of course, you were the--I believe
2611 you were on Senator Baucus' staff at that time, so I am sure
2612 you remember. So I would like to ask you, Mr. Blum, are you
2613 telling me that the authors of the legislation, of course,
2614 including my father, are wrong when they say that they
2615 intended for CMS not to interfere in these negotiations?

2616 Mr. {Blum.} So going back to my days on the Senate
2617 Finance Committee, I worked with your father and his staff
2618 during the conference committee that produced the final Part
2619 D legislation, and so I understand well the intent of the

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2620 Congress at the time. Senator Baucus, my former boss, and
2621 the team that he had, myself included, were directly involved
2622 in the drafting of the Part D legislation. So I understand
2623 well why Congress chose to put in place the non-interference
2624 clause.

2625 While we understand the disagreement, and it is clear
2626 from this hearing today there is a disagreement, we proposed
2627 the change with the interest to make the provision work
2628 better, to have it be stronger, to make it really clear when
2629 CMS will and won't get involved with contract disputes, with
2630 Part D sponsors and pharmacies. We get asked frequently to
2631 get involved with those disputes, and we want to kind of
2632 articulate to the public when and won't CMS will try and
2633 broker, you know, beneficiary access issues or pharmacy
2634 network issues.

2635 Mr. {Bilirakis.} Okay.

2636 Mr. {Blum.} We will thoroughly review--I look forward
2637 to looking to the CRS documents to understand our authority
2638 to make sure that our legal team understands it, but as I
2639 said several times during this hearing, our intention is not
2640 to interfere with the price--

2641 Mr. {Bilirakis.} Thank you.

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2642 Mr. {Blum.} --negotiations.

2643 Mr. {Bilirakis.} And you understood the intent of the
2644 law then, and now you understand it as well.

2645 Mr. {Blum.} Having served on the Finance Committee
2646 staff during the 2003 drafting, I understand the 2003
2647 legislation--

2648 Mr. {Bilirakis.} Thank you.

2649 Mr. {Blum.} --well.

2650 Mr. {Bilirakis.} Thank you, sir, because I don't have a
2651 lot of time, I want to get onto the next question.
2652 Appreciate it.

2653 You justify some of the changes in the rule as a means
2654 to address prescription drug abuse. It seems to me that we
2655 would--could manage some of the prescription drug problem
2656 through the use of a pharmacy lock, the lock-in program,
2657 where a single point of sale could provide more protection
2658 against the problem of doctor shopping, pharmacy shopping,
2659 and inappropriate drug therapies for high-risk beneficiaries.
2660 Pharmacy lock-in has been used successfully in State
2661 Medicaid, of course, as you know, and also with Tricare and
2662 commercial insurance. Are you in support of pharmacy lock-
2663 in, sir?

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2664 Mr. {Blum.} I have testified on the record last summer
2665 to the Senate Homeland Security Committee that we believe
2666 lock-in provisions can help to reduce inappropriate
2667 prescribing, prescriber fraud. We have concluded that
2668 Congress would have to act to authorize us to allow pharmacy
2669 lock-in, but we believe that is a change that Congress should
2670 make.

2671 Mr. {Bilirakis.} So in other words, you agree with the
2672 pharmacy lock-in. Why isn't it in this particular rule?

2673 Mr. {Blum.} We don't have the authority for that
2674 change. I testified that Congress would have to get the--
2675 give us that authority.

2676 Mr. {Bilirakis.} Okay. I have introduced a bipartisan
2677 Bill on this particular issue, but staff at CMS have not
2678 replied to requests from this committee for technical
2679 assistance on this Bill. Today, would you commit to me, you
2680 personally, to review this legislation that I have offered?
2681 I have actually filed it. It has been about a couple--

2682 Mr. {Blum.} Absolutely.

2683 Mr. {Bilirakis.} --a few months. So I would like to
2684 get your feedback--

2685 Mr. {Blum.} Yes.

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2686 Mr. {Bilirakis.} --with regard to this legislation.

2687 Would you personally commit to me that you will review that
2688 and respond to me?

2689 Mr. {Blum.} Absolutely.

2690 Mr. {Bilirakis.} Okay, thank you very much. Appreciate
2691 that.

2692 Mr. {Pitts.} Chair thanks the gentleman. Chair thanks
2693 Mr. Blum for spending 2 1/2 hours with the subcommittee this
2694 morning. We really appreciate your time and patience. We
2695 will send you additional questions. We ask that you please
2696 respond to those promptly.

2697 There are two things I want to highlight. Dr. Burgess'
2698 question was for the full and complete cost analysis that led
2699 to the rule. If you will provide that. And Mr. Guthrie's
2700 question, the call sheets, the full complaint data that you
2701 referenced that you say shows seniors don't like their Part D
2702 plans, would you provide those to the committee?

2703 Mr. {Blum.} To clarify, the complaint did--2013 CMS
2704 received over 30,000 complaints on various Part D issues. We
2705 have to protect beneficiary confidentiality, but we will do
2706 our best to make sure that we can summarize that data in a
2707 way that would be helpful to this committee.

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2708 {Voice.} Redact the names and let us have it.

2709 Mr. {Pitts.} Go ahead.

2710 {Voice.} Mr. Chairman, I think you can redact the names
2711 and let us have the information.

2712 Mr. {Blum.} We will look into it.

2713 {Voice.} The complaints themselves will be significant.

2714 Mr. {Blum.} Yeah, we will look into it, sir.

2715 {Voice.} Thank you, Mr. Chairman.

2716 Mr. {Pitts.} All right. Chair thanks the gentleman.

2717 We will now take a 5-minute recess as the second panel set
2718 up.

2719 [Recess]

2720 Mr. {Pitts.} Our time of recess having expired, we will
2721 go to our second panel. We have three witnesses on our
2722 second panel today. We have Mr. Douglas Holtz-Eakin,
2723 President, the American Action Forum; Mr. Carl Schmid, Deputy
2724 Executive Director, The AIDS Institute; Mr. Joe Baker,
2725 President of the Medicare Rights Center. Thank you all for
2726 coming. You will each have 5 minutes to summarize your
2727 testimony. Your written testimony will be placed in the
2728 record.

2729 Mr.--or Dr. Eakin, you are recognized for 5 minutes for

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2730 your opening statement.

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2731 ^STATEMENTS OF DOUGLAS HOLTZ-EAKIN, PRESIDENT, AMERICAN
2732 ACTION FORUM; CARL SCHMID, DEPUTY EXECUTIVE DIRECTOR, THE
2733 AIDS INSTITUTE; AND JOE BAKER, PRESIDENT, MEDICARE RIGHTS
2734 CENTER

|

2735 ^STATEMENT OF DOUGLAS HOLTZ-EAKIN

2736 } Mr. {Holtz-Eakin.} Well, thank you, Chairman Pitts, and
2737 Ranking Member Pallone, members of the committee, for the
2738 privilege of being here today to discuss what I consider to
2739 be a crucial proposed rule from CMS.

2740 You have my written statement. Let me make just a few
2741 brief points at the outset. First, as has been discussed,
2742 the Part D Program has a tremendous record of success. It
2743 has come in well below the projected budget costs, and I note
2744 with irony that Mr. Blum said one reason to do this rule is
2745 CBO was saying it is going to cost so much in the future,
2746 when it came in at \$55 billion, after my CBO projected it
2747 would cost \$122 in 2012.

2748 It also has had stable beneficiary premiums, it has a
2749 very high level of beneficiary satisfaction, 85 percent of

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2750 seniors are very happy with Part D. For those who are
2751 interested in the statistics on this, I will point out 30,000
2752 complaints is less than 1/10 of a percent of Medicare
2753 beneficiaries. So we have approval at 85, complaints at
2754 under 1/10 of 1 percent. And seniors have, in 2013, at least
2755 23 choices in every plan area. And so that record of success
2756 is not an accident. If you think about how Part D works, the
2757 plans sit in the middle and the plan sponsors, and they
2758 negotiate with the drug manufacturers discounts on their
2759 drugs on the basis of a volume of business they can deliver.
2760 And to do that, over here they go out and offer different
2761 plans with different formularies, to to confuse seniors, but
2762 to attract more volume and get better deals over here, and
2763 they develop these preferred pharmacy networks with special
2764 provisions, again, by offering lower prices, they get more
2765 volume, they get more ability to negotiate over here with the
2766 drug manufacturers. That capacity to undertake these
2767 negotiations is at the heart of the success of Part D. And
2768 for Mr. Blum to suggest that by setting a saving standard--a
2769 minimum saving standard, that you have to get in a preferred
2770 pharmacy network, that is a direct intervention in the price
2771 negotiation for those pharmacies, and to suggest that you

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2772 offer to someone you have never negotiated with exactly the
2773 same deal you have given to somebody you have negotiated
2774 with, that is a direct intervention of the negotiations. I
2775 believe that the idea that this is not violating
2776 Congressional intent with the non-interference clause is just
2777 transparently false. I mean I was there at the birth of the
2778 Part D benefit, as were many in this committee. This is just
2779 flatly inconsistent with what Congress intended.

2780 I am not a lawyer, so I don't know about the statutory
2781 authority, but the lawyers I have consulted with say they
2782 don't have the authority to do this. And for Mr. Blum to
2783 suggest that it somehow strengthens the non-interference
2784 clause is just Orwellian doublespeak, and I am deeply
2785 troubled by the fact that they would do this.

2786 The implications, I think, are very important. First,
2787 and this is your self-interest, if they get--if they do this
2788 in Part D, they don't need you anymore. Not this committee,
2789 not the full committee, not the House, not the Senate, not
2790 the Congress. They can do whatever they want with the Part D
2791 benefit, and I believe that is an inappropriate power for an
2792 Administration to have. And it would also hurt the Program
2793 as a whole because if you are a plan sponsor, and you have an

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2794 Administration that has the power to do whatever it wants
2795 without real consideration of the consequences, you are
2796 either not going to participate or you are going to charge a
2797 lot to participate, and that is going to hurt the seniors,
2798 which, in the end, are the focal point of the Program.

2799 So I believe those provisions are ones that certainly
2800 cannot be rushed through in the next couple of weeks. It
2801 shouldn't happen at all, and I would urge the committee to do
2802 everything in their power to stop them.

2803 The other features of the rule, there are many details
2804 in here, but limiting the number of plans qualms the
2805 negotiations that they can do with the drug manufacturers.
2806 As a result, there is no real way that CMS can claim to be
2807 monitoring savings in the program by looking at one half of
2808 this equation. That is incomplete and incorrect, and any
2809 support for this rule on that basis has to be questioned.
2810 They need to provide a lot better support, as in the cost
2811 analysis that you mentioned. I think that overall there have
2812 been some private estimates to suggest the limiting in
2813 choice, the limiting competition is going to raise plan bids
2814 by about 10 percent. That may not directly translate into 10
2815 percent higher premiums for beneficiaries, but those 10

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2816 percent costs will go somewhere in the system. That is bad
2817 news for taxpayers, bad news for beneficiaries, or both, and
2818 we need to be concerned about that.

2819 There is no question that I think this leads to higher
2820 budget costs for a program that has consistently surprised on
2821 the downside, and, you know, we have had a lot of discussion,
2822 this is going to restrict some seniors' access to their
2823 doctors and/or their particular pharmaceuticals, and those
2824 are steps in the wrong direction from the point of view of
2825 the Program.

2826 I guess the last thing I would close with is there has
2827 been a lot of discussion about seniors getting in the right
2828 plan. It is not as if there is no other way to do that.
2829 This is a terrible way to solve that problem. Mr. Blum runs
2830 a Web site called Mediare.gov, with a plan finder. He might
2831 want to devote his efforts to improving that.

2832 Thank you.

2833 [The prepared statement of Mr. Holtz-Eakin follows:]

2834 ***** INSERT 2 *****

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|

2835 Mr. {Pitts.} Chair thanks the gentleman. Now

2836 recognizes Mr. Schmid for 5 minutes for an opening statement.

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2837 ^STATEMENT OF CARL SCHMID

2838 } Mr. {Schmid.} Thank you. Good afternoon.

2839 The AIDS Institute is pleased to offer our views on
2840 CMS's proposed Medicare Part D rule. Since we believe
2841 aspects of the proposed rule would erode a patient's ability
2842 to obtain the medications that their providers prescribed, we
2843 are urging CMS to scrap the proposal to change the 6
2844 protected classes.

2845 Frankly, just like many of you, we were rather surprised
2846 the Obama Administration would propose such a rule, given its
2847 strong commitment to quality healthcare, including mental
2848 health, and to others living with illnesses and diseases.

2849 For people with HIV, and so many other patients, new
2850 drug therapies have saved millions of lives, and prolonged
2851 millions more. The advent of antiretroviral medications in
2852 the late '90's turned HIV from a near certain death to a more
2853 manageable disease if patients have access to quality care
2854 and medications.

2855 We know all medications are not the same, and each
2856 person reacts differently to a particular drug. Doctors and

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2857 patients together make careful decisions about which
2858 therapies are most appropriate on a case-by-case basis. Some
2859 individuals may develop side-effects to a particular drug,
2860 while another may need a therapy to avoid a harmful
2861 interaction for a drug being taken for another health
2862 condition. For people with HIV, drug resistance can occur,
2863 requiring them the ability to switch to another drug without
2864 interruption.

2865 It is for these reasons, when Medicare Part D was first
2866 implemented, CMS determined that a minimum of only 2 drugs in
2867 the class, which is what the law requires, was simply not
2868 enough for certain patients, including those with HIV, mental
2869 illness, cancer, epilepsy, and those undergoing organ
2870 transplantation. The 6 Protected Classes was created so that
2871 patients could have access to all the drugs in these classes.

2872 For the past 10 years, Medicare Part D has been working
2873 for millions of seniors and people with disabilities,
2874 including over 100,000 people a year with HIV. As part of
2875 the Affordable Care Act, Congress even codified the 6
2876 protected classes. We see no reason why the protected
2877 classes should be changed, and if they were, we would like to
2878 see more classes of drugs gain protected status rather than

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2879 reducing them, so that more patients can gain access to the
2880 medications prescribed.

2881 As I commented earlier, we were shocked when we read the
2882 proposed rule. The Secretary used the authority granted to
2883 her under the ACA to develop criteria to alter the 6
2884 protected classes, and, at the same time, proposed to
2885 eliminate 3 of them. One would think if the Administration
2886 was contemplating any changes, their criteria for class
2887 review would be developed first with adequate public comment
2888 before it was applied. Instead, a very arbitrary criterion
2889 was developed in secret, and then arbitrarily applied at the
2890 same time.

2891 Thankfully, the proposed rule continues the protections
2892 for antiretrovirals. That would not be the case for
2893 antidepressants and immunosuppressants in 2015, and
2894 antipsychotics in 2016, if the proposed law--proposed rule
2895 was finalized.

2896 Frankly, we are worried. Who will be next? How much
2897 longer will people with HIV, cancer and epilepsy have access
2898 to all the medications they need through Medicare Part D?

2899 Because it is estimated that about 1/2 the people living
2900 with HIV experience mental illness or substance abuse, we are

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2901 concerned that people with HIV who rely on antidepressants
2902 and antipsychotics will not be able to access their
2903 medications. We are also concerned that people with
2904 Hepatitis, who we also advocate for, who undergo liver
2905 transplants, will not be able to access their
2906 immunosuppressants.

2907 Medicare Part D, including the 6 protected classes, is
2908 working. It is enabling the elderly and the disabled to
2909 access the medications their providers prescribe, and at the
2910 same time, saving and prolonging countless lives. We need--
2911 see no reason to change the protected classes, and urge this
2912 --the Administration to withdraw this proposal.

2913 We are encouraged by CMS statements this morning they
2914 are--that they are sensitive to and are carefully listening
2915 to our concerns. Hopefully, in the end, they will do the
2916 right thing for patients.

2917 Thank you.

2918 [The prepared statement of Mr. Schmid follows:]

2919 ***** INSERT 3 *****

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|

2920 Mr. {Pitts.} Chair thanks the gentleman. Now recognize

2921 Mr. Baker for 5 minutes for an opening statement.

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2922 ^STATEMENT OF JOE BAKER

2923 } Mr. {Baker.} Thank you, Chairman Pitts, and Ranking
2924 Member Pallone, for the--thank you, Chairman Pitts, and
2925 Ranking Member Pallone, for the opportunity to testify today
2926 on the proposed rule for Medicare Advantage and Part D
2927 prescription drug plans.

2928 Excuse me. As you know, the Medicare Rights Center is
2929 the national nonprofit that works to ensure access to people
2930 with Medicare, both older adults and people with
2931 disabilities. We answer over 15,000 questions each year from
2932 beneficiaries, family, caregivers and professionals, and our
2933 Online resources receive more than 1 million visits annually.

2934 I want to stress 3 key points today. First, we believe
2935 that each one of the proposed policies reflected in this rule
2936 should be evaluated on its own merits, as opposed to
2937 supporting or redirecting the entire rule as a whole. We
2938 note that the comment period, as has been said, for the rule
2939 is still open, and all interested parties should submit
2940 comments and give CMS a chance to modify the rule based upon
2941 those comments.

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2942 In this spirit, I would like to talk about a couple of
2943 provisions that we strongly support, and others that we do
2944 oppose.

2945 Second, I think the rule reflects CMS's belief that
2946 increased oversight and monitoring is required to ensure that
2947 Medicare Advantage and Part D plans are adequately serving
2948 people with Medicare. We wholeheartedly agree with this
2949 determination. In particular, we strongly support CMS's
2950 proposal to ensure meaningful differences among Part D plans
2951 by further consolidating plan options. On our helpline, we
2952 observed that older adults and people with disabilities find
2953 choosing among a large number of Part D plans to be a
2954 dizzying experience. Most people with Medicare fail to re-
2955 evaluate their coverage options on an annual basis.
2956 According to one analysis from 2006 to 2010, only 13 percent
2957 of beneficiaries switch prescription drug plans during each
2958 annual enrollment period, despite changes in premiums, cost
2959 sharing and coverage.

2960 So ensuring that there are real meaningful differences
2961 between offerings from the same plan sponsor reduces
2962 confusion and helps people better comparison shop.

2963 Further related to Part D, CMS acknowledges that

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2964 Medicare Advantage plans with prescription drug coverage are
2965 not adequately coordinating beneficiary care with respect to
2966 drug denials. When a Part D drug is denied because it should
2967 be covered by Part A or B of the plan, CMS finds that some
2968 plans are not adequately informing beneficiaries that their
2969 drugs should be covered. This indicates that some plans are
2970 not living up to their promise to coordinate care efficiently
2971 for their members. To fix this, CMS appropriately suggests
2972 new requirements for plans to facilitate access to these
2973 medicines.

2974 Throughout the proposed rule, CMS demonstrates a
2975 commitment to enhancing transparency. For instance,
2976 increased transparency is at the heart of proposals
2977 concerning drug pricing fairness, and accuracy with respect
2978 to preferred pharmacy. CMS also aims to make information
2979 about annual changes to Medicare Advantage and Part D plans
2980 more transparent throughout proposals to strengthen
2981 beneficiary notices ahead of and during the annual enrollment
2982 period. We support these proposals.

2983 Finally, CMS aims to increase oversight and monitoring
2984 of prescribing providers to address problems with Medicaid--
2985 medication diversion and abusive practices. We appreciate

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2986 the rule's aim that--and that it avoids placing burdensome
2987 restriction on beneficiary access to needed medicines, but we
2988 would like to see additional beneficiary protections in any
2989 new system.

2990 Third, we are deeply concerned about CMS's proposed
2991 policy to scale-back the protected classes. Specifically,
2992 CMS argues that existing beneficiary protections, including
2993 the Part D appeals process, will preserve access for
2994 beneficiaries if open formulary access is relaxed for
2995 antidepressants, antipsychotics and immunosuppressants.
2996 Based on our experience counseling Medicare beneficiary, we
2997 believe these protections are insufficient, especially the
2998 Part D appeals process. Echoing our experience, the 2011
2999 data released by CMS finds that over half of plan-level
3000 denials are overturned by the independent review entity; the
3001 first time an entity other than plan--the plan reviews the
3002 appeal. This alarming rate of reversal raises serious
3003 questions about how well the appeals process is working, and
3004 demands greater transparencies. We urge members of Congress
3005 request that CMS make plan-level appeals data accessible so
3006 that targets for improvement can be identified. In addition,
3007 Congress should encourage CMS to improve the Part D appeals

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3008 process, first and foremost by allowing a beneficiary to
3009 receive a formal denial from the Part D plan at the pharmacy
3010 counter, as opposed to expecting beneficiaries and their
3011 doctors to submit a formal request to the plan for the denial
3012 before the appeals process can begin.

3013 Finally, we do believe that pricing is an issue, and CMS
3014 is trying to get at that through this proposal. We believe
3015 that Congress should restore Medicare drug rebates for
3016 beneficiaries that are dually eligible for both Medicare and
3017 Medicaid, which would save taxpayers over \$140 billion over
3018 10 years.

3019 Thank you for this opportunity to testify.

3020 [The prepared statement of Mr. Baker follows:]

3021 ***** INSERT 4 *****

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3022 Mr. {Pitts.} Chair thanks the gentleman. And we will
3023 now go to questioning. I will recognize myself 5 minutes for
3024 that purpose.

3025 Dr. Holtz-Eakin, in a recent final regulation issued in
3026 April 2011, CMS reiterated the non-interference clause's
3027 application to Part D, sponsor pharmacy negotiations, in its
3028 response to a comment, ``As provided in Section 1860D-11(i)
3029 of the Act, we are prohibited from interfering with
3030 negotiation between Part D plans and pharmacies.''

3031 Dr. Holtz-Eakin, you were at CBO during the time that
3032 the Part D Program was operating. How did CBO interpret the
3033 non-interference clause that Congress passed in 2003?

3034 Mr. {Holtz-Eakin.} Well, we were asked on numerous
3035 occasions what would happen if the non-interference clause
3036 were to be deleted from the law, and indeed shortly after its
3037 passage, this is a letter from January 23, 2004, we wrote a
3038 letter to then-Majority Leader Frist, which said that
3039 striking the provision would affect negotiations between drug
3040 manufacturers and pharmacies and sponsors of prescription
3041 drug plans. So there is no question that it covered the
3042 pharmacies, and there is no question that the kind of action

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3043 that CMS is proposing in this rule is at odds with the intent
3044 of Congress.

3045 Mr. {Pitts.} In the proposed regulation, CMS has
3046 reinterpreted the non-interference clause, clearly outlined
3047 in federal law, such that, in my opinion, the proposed
3048 regulation actually contradicts the meaning of the statute.

3049 If CMS can effectively change the meaning of settled
3050 federal law via regulation, then we must ask ourselves what
3051 are the outrebounds of the abuse of that authority.

3052 Dr. Holtz-Eakin, could CMS require pharmacies or
3053 manufacturers to give them records access?

3054 Mr. {Holtz-Eakin.} Certainly, they could, and I don't
3055 know what the outrebounds are, Mr. Chairman. I am not
3056 certainly a lawyer by training, but, you know, the clear
3057 intent was to not do what is proposed in this rule, and if
3058 they are to go forward with this and not see it struck down
3059 by the courts, which I think it very well would be, then
3060 there is nothing they can't do to the Part--

3061 Mr. {Pitts.} Could--

3062 Mr. {Holtz-Eakin.} --Part D--

3063 Mr. {Pitts.} Could CMS set volume caps on prescriptions
3064 under Part D?

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3065 Mr. {Holtz-Eakin.} They certainly could.

3066 Mr. {Pitts.} Could CMS require participating pharmacies
3067 maintain stockpiles of certain drugs?

3068 Mr. {Holtz-Eakin.} Yes, they could.

3069 Mr. {Pitts.} The Office of the Actuary at CMS produced
3070 an analysis of the estimated budgetary impact of the proposed
3071 rule, yet they acknowledged in conversations with committee
3072 staff that not all elements of the proposed rule had been
3073 scorned.

3074 Well, Milliman actually did a complete cost analysis by
3075 surveying drug plan sponsors and PBM's to evaluate the
3076 anticipated effect of the rule on the Part D Program, and
3077 found it would cost billions of dollars. Do you believe that
3078 the American public deserves a full cost accounting from CMS
3079 on this issue?

3080 Mr. {Holtz-Eakin.} I do. I believe this rule is so
3081 sweeping as to essentially constitute new law, that Congress
3082 ask for a budgetary analysis from the CBO before it enacts
3083 new law, I think the same thing should be done in this case.

3084 Mr. {Pitts.} CMS rule proposes that prescription drug
3085 plans are limited to offering only 1 standard benefit, and 1
3086 enhanced benefit plan per region, is that correct?

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3087 Mr. {Holtz-Eakin.} That is correct.

3088 Mr. {Pitts.} So let me ask this, if 2 of my
3089 constituents are enrolled in 2 different enhanced benefit
3090 plans offered by the same PDP, 1 of those 2 seniors will lose
3091 their current prescription drug plan under the proposed rule,
3092 isn't that correct?

3093 Mr. {Holtz-Eakin.} That is correct, and in my written
3094 testimony, we have an estimate of the number of seniors who
3095 would be affected in each state.

3096 Mr. {Pitts.} Well, I don't think CMS should be
3097 outlawing seniors' current prescription drug plans by placing
3098 arbitrary caps on the number of plans that can be offered.
3099 CMS should not be taking away the prescription drug plans
3100 that seniors rely on today, do you agree?

3101 Mr. {Holtz-Eakin.} I agree with the principle that
3102 seniors should be able to choose, that choice is an important
3103 part of our society.

3104 I want to emphasize one of the things I said in my
3105 opening. You can't look at that in isolation. The ability
3106 to have more plans, gets you more volume and lowers the cost
3107 of the Program as a whole. And I think the CMS analysis is
3108 fundamentally flawed by ignoring that.

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3109 Mr. {Pitts.} All right, thank you. Chair recognizes
3110 the Ranking Member, Mr. Pallone, 5 minutes for questions.

3111 Mr. {Pallone.} Thank you, Mr. Chairman.

3112 I wanted to ask Mr. Baker, when Part D was enacted into
3113 law, many of us were skeptical the Program would work. In
3114 fact, we were opposed to turning Medicare over solely to
3115 private insurance companies because of concerns with gaming
3116 and the ability to fully protect beneficiaries in these plans
3117 that may be more interested in corporate profits than patient
3118 wellbeing.

3119 Nevertheless, once Part D became the law, Democrats put
3120 aside their reservations and have worked hard to ensure that
3121 patients get the best deal possible under the law. And I
3122 would contrast this with the way the Republicans have behaved
3123 since the enactment of the Affordable Care Act, actively
3124 trying to undermine implementation of the law and keep
3125 consumers from getting access to important program benefits.
3126 However, the Affordable Care Act made a number of
3127 improvements to Part D, most importantly, it filled in the
3128 donut hole, and the ACA also made a number of changes to the
3129 Medicare Advantage Program, ensuring that consumers and
3130 taxpayers get good value for their dollars.

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3131 So, Mr. Baker, could you talk briefly about the way the
3132 Affordable Care Act has improved Part D and Medicare
3133 Advantage for beneficiaries?

3134 Mr. {Baker.} Well, once again, you are absolutely
3135 right. The closure of the donut hole has been a great boom
3136 to people with Medicare Part D coverage, and we hear about
3137 that on our helpline. As well, with regard to the changes in
3138 the Medicare Advantage Program that have been implemented
3139 through the Affordable Care Act, I note the wellness visit
3140 that is now covered, preventive care that is now covered, the
3141 prohibition about charging higher coinsurance or copayment
3142 amounts for care, like skilled nursing facility care or
3143 chemotherapy care. This makes sure that there is no gaming
3144 amongst the plans, in trying to provide disincentives for
3145 folks with, for example, cancer--a history of cancer from
3146 joining certain plans, from consolidating offerings, once
3147 again, as Mr. Blum referred to, in Part D, but also in the
3148 Medicare Advantage Program, there has been a constant effort
3149 by CMS under the Affordable Care Act to make sure the plans
3150 have meaningful differences. And so that has helped
3151 consumers understand the program better and use the program
3152 better, I think. And finally, the out-of-pocket cap that CMS

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3153 has implemented in the Medicare Advantage Program has
3154 provided seniors with, I think, great security in knowing
3155 that, yes, they have copayments amount but their--copayments
3156 amount in Medicare Advantage plans, but they will be capped
3157 at a certain amount out-of-pocket, and I think that has done
3158 a lot to make the program more attractive to seniors. They
3159 flock to Medigap Programs in the context of original Medicare
3160 because they see a lot of financial security there for that
3161 first dollar of coverage. I think many now see the out-of-
3162 pocket maximum to Medicare Advantage as a similar financial
3163 security measuring, and so that has made the program more
3164 attractive.

3165 Mr. {Pallone.} I know that you expressed significant
3166 concern with the section of the rule related to categories or
3167 classes of drugs of clinical concern and which identify
3168 classes of drugs require Part D plans to include all or
3169 substantially all covered drugs on their formularies. And
3170 you are aware, CMS has indicated that these protected classes
3171 of drugs were not necessarily meant to be permanently
3172 protected, recognizing now on the one hand in many instances
3173 as generics become available, broadly mandating that every
3174 drug be available may not make sense, but on the other hand,

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3175 new classes of drugs may need to be deemed protected to
3176 ensure patient access. And as such, the Secretary was
3177 directed to establish criteria by which identified classes,
3178 including new classes of drugs for inclusion under the
3179 protected status.

3180 If you could--I know you are concerned about the Part D
3181 appeals process. Do--can you just basically describe some of
3182 the problems that you see with the current appeals process,
3183 and why, if the appeals process is not fixed, the protected
3184 classes proposal would be especially problematic for
3185 patients?

3186 Mr. {Baker.} Yes, I would be happy to. You know, first
3187 off, this issue that I mentioned earlier about when folks go
3188 to the pharmacy counter, they get a denial, and in effect,
3189 they are told their drug is not going to be covered and be
3190 dispensed to them, but that is not an ``actual denial'' by
3191 the plan. It is not a coverage determination. They then
3192 need to either go home or otherwise call or email or somehow
3193 contact the plan to actually get a coverage determination and
3194 denial, and this can take a lot of time, it can take a lot of
3195 calls. So we are really calling for that denial at the plan
3196 counter to be the denial or coverage determination that does

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3197 help them initiate and allow them to initiate an appeal. So
3198 that is one issue there.

3199 There are also then 2--at least 2 levels of
3200 redetermination that the plan has in addition to that denial
3201 at the pharmacy counter. We believe that could be slimmed to
3202 get to the independent review entity sooner. I think also we
3203 are also concerned generally that there is not a lot of data
3204 about how plans internally are dealing with appeals, and we
3205 think that information, some of it could be publicly
3206 available, and could help consumer gage whether or not plans
3207 are doing a good job by those who have problems with the
3208 plans' determinations.

3209 Mr. {Pallone.} All right, thanks a lot.

3210 Mr. {Pitts.} Chair now recognizes Vice Chairman of the
3211 Committee, Dr. Burgess, 5 minutes for questions.

3212 Dr. {Burgess.} And I thank the Chairman.

3213 I would offer for those limited comparisons between ACA
3214 and the Medicare Modernization Act from 10 years ago. There
3215 are some significant differences, of course. The Medicare
3216 Modernization Act was not the coercive, broad, overreaching
3217 legislation that the ACA was. There was difference in scope
3218 and size, and thus, the implementation, while there may be

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3219 similarities, there are also vast differences.

3220 Mr. Schmid, just like you, I was--to say I was
3221 blindsided by this rule would be an understatement. I
3222 thought things were working reasonably well. I don't
3223 understand the discussion, why we are even having the
3224 discussion about dispensing with any of the 6 protected
3225 classes. And Dr. McClellan came here and very patiently, in
3226 2005 and 2006, very patiently went through what the reasons
3227 were for developing those classes. I think you heard Dr.
3228 Murphy talk about the--on the psychiatric side. I have
3229 discussed on the immunosuppressant side. You have very
3230 eloquently discussed on the--with the antiretroviral drugs,
3231 why these are important to have these as protected classes.
3232 And I really cannot--and I don't--I did not hear from Mr.
3233 Blum why there was a reason for doing this, so I agree with
3234 you. I am completely blindsided by the rule.

3235 Dr. Holtz-Eakin, I mean Chairman Pitts asked you this to
3236 some degree already, but let me just ask you again. What--in
3237 your opinion, what was the original intent of the non-
3238 interference clause?

3239 Mr. {Holtz-Eakin.} Its intent was to make sure that, on
3240 both sides of the negotiations, that plans had the unfettered

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3241 ability to negotiate with--aggressively with drug
3242 manufacturers, and to structure their plans and their
3243 pharmacy networks to attract the volume necessary to get good
3244 deals with the manufacturers. And the idea was to keep the
3245 Congress and the Administration out of those negotiations.

3246 Dr. {Burgess.} So if we are doing away with the non-
3247 interference clause, perhaps we are instituting an
3248 interference clause. Would that be the--a logical
3249 assumption?

3250 Mr. {Holtz-Eakin.} I view this as direct interference
3251 in negotiations. I don't see any other way to read it. If I
3252 negotiate with you, and then turn around and CMS orders me to
3253 give him the same deal, that is a pretty clear interference.
3254 I don't understand that.

3255 Dr. {Burgess.} Well, of course, Congress loves to
3256 interfere, so that will give us an opening.

3257 Mr. {Holtz-Eakin.} I would encourage you to restrict
3258 those impulses please.

3259 Dr. {Burgess.} Well, that--of course, the--that is, of
3260 course, why we are having this discussion, but it would--I
3261 mean that interference--then if we label that the
3262 interference clause, the interference clause is going to have

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3263 an effect on the direct cost to beneficiaries, is it not?

3264 Mr. {Holtz-Eakin.} It is. I mean the core costs are

3265 the pharmaceuticals, and the deal that can be cut with the

3266 manufacturers is at the heart of the cost of the program.

3267 Things that impair the ability of plans to cut good deals are

3268 going to raise the cost to everybody; beneficiaries,

3269 taxpayers, it is going to show up somewhere.

3270 Dr. {Burgess.} And I was going to make that point. It

3271 is not just the beneficiaries, obviously, the person who is

3272 ultimately paying the bill, which is the United States

3273 taxpayer, or our generations to follow, since some of it is

3274 not paid for immediately, they will all be affected by the

3275 institution of an interference clause where none existed

3276 before. Is that a correct statement?

3277 Mr. {Holtz-Eakin.} That is correct.

3278 Dr. {Burgess.} So the proposed CMS rule suggests that,

3279 for a competitive market to function, that they, Center for

3280 Medicare and Medicaid Services, has a duty to ensure that

3281 there is a competitive market, and encourage elements to

3282 promote competition. So maybe as a professor in economics,

3283 you can tell us how this interference would promote

3284 competition.

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3285 Mr. {Holtz-Eakin.} I don't think it is pro-competitive.

3286 If you take, for example...

3287 Dr. {Burgess.} Well, but between members of Congress,

3288 wouldn't it?

3289 Mr. {Holtz-Eakin.} Well, just for a second. Just a
3290 narrow provision, you know, the idea that any pharmacy should
3291 be able to provide at the terms negotiated between and plan
3292 and its preferred pharmacy network, there is already
3293 competition. Anyone can right now go to any pharmacy and get
3294 their prescription filled. They may not get the terms from
3295 the preferred network but they can go. That forces those who
3296 are not in the network to compete on non-priced grounds;
3297 service, variety of things in the store, whatever it may be.
3298 That is how economics works. For this--for them to step in
3299 and interfere undercuts that competition.

3300 Dr. {Burgess.} And I, again, don't mean to interrupt
3301 you, but the time will draw short.

3302 And that competition is what gave us the \$4 prescription
3303 at Wal-Mart, and then other chains followed suit with that.
3304 Those are indirect effects of the Medicare Part D law that
3305 oftentimes don't get--no one discusses. So--

3306 Mr. {Holtz-Eakin.} Yeah, I think that is one of the

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3307 reasons it came in under budget cost. I mean the--we thought
3308 the competitive incentives were quite strong with CVL, we
3309 did, but a couple of things happened that we didn't
3310 anticipate. One is we never had any trouble getting sponsors
3311 to enter. There was a fear of having to have government
3312 fallback plans, those were priced in there. None of that
3313 ever happened, however competitive incentives. And the
3314 second was the network size, the pharmacy and the savings in
3315 the pharmacies were bigger than we expected.

3316 Dr. {Burgess.} And just as a consequence to that, I
3317 mean and Mr. Blum testified to the fact that costs came in
3318 lower, he thought because of generic prescribing. I will
3319 tell you that I think that generic prescribed existed because
3320 of the so-called coverage gap, or donut hole. Now that we
3321 have done away with that, or we will do away with that in
3322 future years, what is going to happen to that driver that
3323 kept costs low?

3324 Mr. {Holtz-Eakin.} Well, and I know you are over, but
3325 briefly, I don't think his reading of the record is correct.
3326 The biggest difference between the projections and reality
3327 was lower enrollment. Fewer bodies are cheaper, and that is
3328 the top thing, not generics. Generics are in there, but

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3329 there was a lot of generic substitution anticipated because a
3330 lot of the patented pharmaceuticals were going to go off
3331 patent over the first 10 years. We knew that so that was
3332 priced in at the outset, so it is not really a surprise in
3333 the data.

3334 Dr. {Burgess.} Very good.

3335 Thank you, Mr. Chairman. I will yield back.

3336 Mr. {Pitts.} The Chair thanks the gentleman. Now
3337 recognize the gentleman from Texas, Mr. Green, 5 minutes for
3338 questions.

3339 Mr. {Green.} Thank you, Mr. Chairman.

3340 Mr. Baker, you have heard from Mr. Holtz-Eakin's
3341 testimony certain estimates suggest that a large number of
3342 beneficiaries would lose their current plan due to CMS's
3343 proposal to level the playing field for pharmacies wishing to
3344 offer preferred cost sharing under a plan's preferred
3345 network. To me, this doesn't sound right. Expanding the
3346 availability of pharmacies can often reduce cost sharing as
3347 long as they can meet negotiated price, only seems to expand
3348 access to other places. And it is reasonable to expect that
3349 allowing any pharmacy to match the competitive prices offered
3350 by preferred pharmacies would result in more competition and

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3351 better access to lower-priced drugs for seniors. It also
3352 would seem to help beneficiaries who prefer to retain trusted
3353 relationships with community providers at their local
3354 pharmacy, as well as beneficiaries who do not have nearby
3355 access to a big box retailer.

3356 And my question, Mr. Baker, can you confirm this line of
3357 reasoning? Has it been your experience that all
3358 beneficiaries can currently access preferred networks and
3359 preferred pricing, or do they--or are some of them left out
3360 in the cold?

3361 Mr. {Baker.} It is our experience that some--in our
3362 written testimony, our longer, written testimony, we do talk
3363 about a woman in Maryland who did not, you know, lost access
3364 to her local pharmacy because they were not able to provide
3365 the preferred pricing that she could get at another pharmacy
3366 where she had not had a 40-year relationship with that
3367 pharmacy. So we do believe that opening up, just as we have
3368 any willing Provider in the general networks in the Part D
3369 plans opening up, that any willing Provider in preferred
3370 networks will expand options and access for consumers, and we
3371 certainly are supportive of that proposal.

3372 Mr. {Green.} So you agree with helping beneficiaries

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3373 get access to more pharmacies that provide reduced cost is
3374 good for those patients?

3375 Mr. {Baker.} Yes, I do.

3376 Mr. {Green.} Okay. It seems that pharmacies who have
3377 contracts today really don't want to compete with community
3378 pharmacies who are prohibited now. Would you comment on
3379 this? Wouldn't allowing participating of any pharmacy who
3380 can meet the plan's terms and prices actually help
3381 competition and improve access for patients?

3382 Mr. {Baker.} I think that, you know, certainly, as Mr.
3383 Holtz-Eakins was saying, there are other components on which
3384 pharmacies can compete at such a service, et cetera, what is
3385 in the front of the house, as it were, and not at the
3386 pharmacy counter, but we do believe expanding access by
3387 allowing community pharmacies and others to be able to match
3388 preferred prices will spur further competition, and certainly
3389 increase access and decrease cost for consumers, and
3390 hopefully for the Program itself.

3391 Mr. {Green.} Well, I would have--I think I remember,
3392 because I was on the committee when we did this in '03, it
3393 was a very long markup, same with the Affordable Care Act,
3394 and I think there was an amendment to this effect that was

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3395 part of that, and I am trying to--I will go back and look at
3396 the records, but I understand that, you know, when we deliver
3397 healthcare for doctors, you know, the office visit is
3398 basically the same, you know, if you go have a certain
3399 procedure, it is basically the same. And, now, granted, we
3400 do have preferred providers on certain things, but that is
3401 not--that is through an insurance policy, not necessarily
3402 through Medicare, but--so anyway.

3403 I want to yield back to--yield my time to the Ranking
3404 Member.

3405 Mr. {Pallone.} Thank you. Mr. Baker, I wanted to ask,
3406 I didn't get a chance, that while you have concerns with the
3407 Protected Classes Policy, you still do believe that many of
3408 the other provisions in the rule that protect patients should
3409 go forward, is that correct?

3410 Mr. {Baker.} Yes, we do.

3411 Mr. {Pallone.} All right, thank you. I yield back.

3412 Mr. {Pitts.} The Chair thanks the gentleman. Now
3413 recognizes the gentlelady from North Carolina, Mrs. Ellmers,
3414 5 minutes for questions.

3415 Mrs. {Ellmers.} Thank you, Mr. Chairman, and thank you
3416 to our panel.

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3417 Dr. Holtz-Eakin, I have a question for you that is North
3418 Carolina-specific. I am very concerned with the number. I
3419 think with this proposed rule has a potential of affecting
3420 over 1/2 million of my seniors. Do you know how many of
3421 those healthcare plans, I mean in your numbers and in your
3422 research, do you know how many plans will be eliminated as a
3423 result of this in North Carolina?

3424 Mr. {Holtz-Eakin.} We have an estimate that we would be
3425 happy to get to you. When we--

3426 Mrs. {Burgess.} Okay.

3427 Mr. {Holtz-Eakin.} --did our analysis, we found out the
3428 number of beneficiaries in North Carolina--

3429 Mrs. {Ellmers.} Um-hum.

3430 Mr. {Holtz-Eakin.} --we then looked at the plans in
3431 North Carolina, especially the large plans, we could identify
3432 those that had preferred pharmacy networks that would be
3433 eliminated--

3434 Mrs. {Ellmers.} Um-hum.

3435 Mr. {Holtz-Eakin.} --or other plans that would be
3436 eliminated, and we can get that to you.

3437 Mrs. {Ellmers.} Great, thank you. I would appreciate
3438 that. You know, back in--there was a Milliman study done, a

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3439 survey analysis in January 2014, CMS Medicare Part D proposed
3440 rule, found that approximately 12.9 million Medicare Part D
3441 beneficiaries currently enrolled in preferred pharmacy PDP's
3442 may experience material premiums and cost sharing increases
3443 in 2015 as a result, on average because of the proposed rule.

3444 Do you think this is right, is it 12.9 million seniors
3445 will be affected this way? What are your thoughts on that?

3446 Mr. {Holtz-Eakin.} I--it doesn't surprise me. I don't
3447 know if the precise estimates--

3448 Mrs. {Ellmers.} Um-hum.

3449 Mr. {Holtz-Eakin.} --the right one, but if you change
3450 the terms the way the rule proposes, there is no--not really
3451 anything known as a preferred pharmacy anymore.

3452 Mrs. {Ellmers.} Yeah.

3453 Mr. {Holtz-Eakin.} So a plan can't go to pharmacy--

3454 Mrs. {Ellmers.} Pretty much just goes to--yeah.

3455 Mr. {Holtz-Eakin.} Right, and so they can't cut as good
3456 a deal, the--

3457 Mrs. {Ellmers.} Um-hum-

3458 Mr. {Holtz-Eakin.} --cost sharing will go away and the
3459 prices--the net price to consumers will go up.

3460 Mrs. {Ellmers.} Which is, you know, exactly what, you

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3461 know, I am hearing today as we are, you know, doing this
3462 subcommittee hearing is there are 2, you know, trains of
3463 thought that somehow we are going to be saving money--

3464 Mr. {Holtz-Eakin.} Right.

3465 Mrs. {Ellmers.} --and yet it is contradicting each
3466 other, that by doing this we are actually going to be saving
3467 money, and yet we keep seeing that it is actually not going
3468 to be the case.

3469 Mr. {Holtz-Eakin.} Right. I would just say that the
3470 committee, I mean this issue has these 2 sides, which is you
3471 want to have the--you know, be able to take terms of a
3472 contract to another pharmacy if you can--

3473 Mrs. {Ellmers.} Um-hum.

3474 Mr. {Holtz-Eakin.} --wouldn't that be great, but can
3475 you cut the--a deal with as good of terms and--

3476 Mrs. {Ellmers.} Um-hum.

3477 Mr. {Holtz-Eakin.} --how does that balance out. There
3478 has been a lot of work done by the Federal Trade Commission
3479 whose sole mandate is to identify pro-consumer aspects of the
3480 competition, and they have found these preferred networks are
3481 very effective in helping beneficiaries and consumers. And I
3482 think the committee should look at that, and I think CMS

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3483 should look at that one.

3484 Mrs. {Ellmers.} Um-hum. Um-hum. Thank you. Mr.

3485 Schmid, I just, you know, in my years as a nurse, certainly,

3486 one of those groups of patients that I have had the honor of

3487 taking care of and come to know, and their families have come

3488 to know, are our HIV and AIDS patients. So first of all, I

3489 just want to thank you for all of the work that the

3490 institution is doing, because you are a vital, vital voice in

3491 how much treatment has advanced for our AIDS patients.

3492 And I just want to ask your opinion. With the

3493 provisions that are being put forward in this proposed rule,

3494 are--is this not going to have a negative effect on our

3495 Medicare Part D patients who especially are receiving AIDS

3496 treatment?

3497 Mr. {Schmid.} Yeah, well, right now they are not

3498 proposing to eliminate, you know, access to antiretrovirals,

3499 but I--as I mentioned in our testimony, we are just concerned

3500 we could be next. And, you know, the criteria that they came

3501 up with, you know, it was very arbitrary, the 7 days, you

3502 know, initiate--

3503 Mrs. {Ellmers.} Um-hum.

3504 Mr. {Schmid.} --medication, you know, the--that will

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3505 result in hospitalization or disability for--

3506 Mrs. {Ellmers.} Um-hum.

3507 Mr. {Schmid.} --a typical patient. They are not

3508 looking at a Medicare patient. Yeah, we are very concerned

3509 and--for the future and the harm that it could have to

3510 patients.

3511 Mrs. {Ellmers.} Um-hum.

3512 Mr. {Schmid.} But most immediately, it would have harm

3513 to those who need immunosuppressants and antidepressants, and

3514 in the future, antipsychotics. And as I said in my

3515 testimony, a lot of people with HIV also have mental health

3516 issues.

3517 Mrs. {Ellmers.} Yes.

3518 Mr. {Schmid.} And so, you know, around 50 percent. So

3519 we are very concerned about access for medications for them.

3520 And then our organizations also advocates for people with

3521 Hepatitis--

3522 Mrs. {Ellmers.} Um-hum.

3523 Mr. {Schmid.} --who undergo--

3524 Mrs. {Ellmers.} Um-hum.

3525 Mr. {Schmid.} --liver transplants, and they need

3526 immunosuppressants as well.

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3527 Mrs. {Ellmers.} Immunosuppressants, absolutely. Thank
3528 you.

3529 And, Mr. Baker, I just have a quick question for you.
3530 You know, the proposed rule changes, CMS actually pointed out
3531 that, you know, there was--in this discussion that has
3532 already gone forward, and hopefully we are going to be able
3533 to have enough time for a future discussion, although I think
3534 that that time is falling short. You know, the safeguards
3535 that are in place, do you feel that these patients are being
3536 safeguarded enough? And, you know, as we have discussed, you
3537 know, the idea that we are actually saving money, I mean, you
3538 know, some of CMS's own findings are showing that this is not
3539 the case. You know, what do you say to that, and I will just
3540 make one point that CMS put forward April 2013. It basically
3541 pointed out, it said negotiated prices--pricing for the top
3542 25 brands and 25 generics in Part D Program at a preferred
3543 retail pharmacy is lower than a non-preferred network
3544 pharmacy.

3545 How do you justify the position that we are actually
3546 going to be saving money when we are already doing that, but
3547 by making these, you know, this proposed rule change, that we
3548 will end up saving more money?

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3549 Mr. {Baker.} I think, you know, there are projections
3550 and--on both sides of the ledger, as it were, from various
3551 actuaries. I mean we certainly think that, given the track
3552 record that Part D has had thus far, and the stewardship that
3553 CMS has been engaged in, that the proposal will lead to lower
3554 costs not only for consumers but also for the Program itself.
3555 And so I think--and that is because of the--any willing
3556 Provider that has been in the pharmacy network overall, we
3557 are thinking that same will happen in the preferred network.

3558 Mrs. {Ellmers.} Um-hum. So we are projecting that, but
3559 we aren't seeing those results though.

3560 Mr. {Baker.} Well, there is a lot of--

3561 Mrs. {Ellmers.} Thank you. And I am--I apologize, Mr.
3562 Chairman. I have gone over my time.

3563 Mr. {Pitts.} Chair thanks the gentlelady. And now
3564 recognizes the gentleman from Maryland, Mr. Sarbanes, 5
3565 minutes for questions.

3566 Mr. {Sarbanes.} Thank you, Mr. Chairman. Thank the
3567 panel.

3568 I wanted to talk first about the consolidation idea
3569 which I think is a good one. I know the premise of Dr.
3570 Holtz-Eakin's perspective is that if you reduce the number of

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3571 options that are available, that undermines competition, that
3572 ends up being a problem in terms of better prices for the
3573 Program, and a better set of offerings for the beneficiary
3574 and so forth, but in order for there to be a competitive
3575 environment, the people making the choices have to feel that
3576 they can choose 1 over the other. And my understanding, Mr.
3577 Baker, is that the evidence suggests that when seniors have
3578 that opportunity to make a change, they are so typically
3579 overwhelmed by the number of options that are available, that
3580 they just choose to stick with the plan they have. And the
3581 competition that you want to encourage among the providers,
3582 among the plans, is both with respect to any new
3583 beneficiaries that are coming in, but also more so with the
3584 existing pool because that is the bigger part of the
3585 opportunity.

3586 So if, as a practical matter, seniors are coming and
3587 saying, well, I am in this plan, and yeah, I can go choose a
3588 different one, but I am not going to sit here and go through
3589 all of these different offerings, then the market is not
3590 really working. I mean the assumptions that your perspective
3591 are based on don't hold. And so if you reduce and
3592 consolidate this dizzying array of options that are

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3593 available, you may actually get more people choosing
3594 something different, which will send a signal to the plans
3595 that are offering these opportunities that they have to
3596 compete more robustly.

3597 Now, moving to the issue of the preferred pharmacy
3598 providers and so forth. I think it is outrageous that there
3599 --you have independent community pharmacists that are
3600 essentially being locked out of the opportunity to
3601 participate in a preferred pharmacy network, even when they
3602 are willing to accept the same terms. In a way that is
3603 happening, and I had the benefit of pharmacists in my
3604 district in Halethorpe, which I represent, a fellow named
3605 George Garmer who actually came and sat with me and kind of
3606 took me through his experience, and it may even be that the
3607 Maryland woman you are talking about was one of his
3608 customers, because it sounds very much the same, but she
3609 really couldn't stick with his pharmacy because the way the
3610 copayments were being differentiated between those who were
3611 able to be in the preferred pharmacy network and his
3612 situation meant that she was going to pay another \$300 a year
3613 if she wanted to continue to go to the pharmacy that she had
3614 been going to for 40 years, and where she had a relationship.

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3615 So getting to this issue of the market and how it works,
3616 there is the theory and there is the practice. And I notice
3617 that in your testimony, you made the statement, Mr. Baker,
3618 that with this kind of pharmacy provider network
3619 manipulation, plans distort market behavior by lowering
3620 beneficiary cost sharing where the full cost of the drug is
3621 the same or higher than it would be at non-preferred
3622 pharmacy. And this is important. Instead of harnessing the
3623 power of consumer choice to lower costs overall by aligning
3624 lower cost sharing with lower total costs, the plans divide
3625 the interests of individual beneficiaries on the one hand,
3626 and the Medicare Program on the other, in order to increase
3627 the profits of related entity mail-order pharmacies. That is
3628 not the way it should work, and I just want to give you
3629 another opportunity because I feel pretty passionately about
3630 this, just based on this particular constituent who came and
3631 brought it to my attention, if you could speak again as to
3632 why this is a distortion of the market that we are supposedly
3633 trying to encourage here.

3634 Mr. {Baker.} Right. I think the distortion is exactly
3635 as you said, and that is that these lower cost sharing for
3636 beneficiaries into these preferred networks is not matched

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3637 by, in many instances, in some instances by actual lower
3638 prices for the Program. And so you are, you know, steering,
3639 if you will, beneficiaries to higher cost pharmacies that are
3640 either chain pharmacies or pharmacies that are wholly or
3641 partially owned by the plans themselves. And plans are
3642 reaping and pharmacies are reaping profits from that.

3643 We really think that the interests of the Program and
3644 beneficiaries should be aligned, not only for lower prices,
3645 but also because beneficiaries care about the sustainability
3646 of the Medicare Program and of this benefit, and to the
3647 extent that there can be that win-win, and also at the same
3648 time allowing community pharmacists into the equation to
3649 provide the services that they have been providing, you have
3650 more access at lower prices.

3651 Mr. {Sarbanes.} My time is up, but I will just note
3652 that if you have more transparency, it will promote better
3653 alignment, I think--

3654 Mr. {Baker.} Yes.

3655 Mr. {Sarbanes.} --by definition. Thank you.

3656 Mr. {Pitts.} Chair thanks the gentleman. Now
3657 recognizes the gentleman from Virginia, Mr. Griffith, 5
3658 minutes for questions.

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3659 Mr. {Griffith.} Thank you, Mr. Chairman. And, Mr.
3660 Chairman, I appreciate you having this hearing, and this is,
3661 you know, one of those hearings where it has put me into a
3662 dilemma of sorts because I have great concerns that CMS
3663 doesn't have the authority to do a lot of things that they
3664 are doing in this rule-making process, and I noted with
3665 interest Dr. Gingrey earlier brought up the report from the
3666 CRS, and one of the things that he didn't mention is that,
3667 you know, what they are attempting to do is to take the
3668 legislative language and shift an and to an or, and that
3669 causes me as an attorney, who believes that the agencies all
3670 to do with the law says, and if there is a problem come back
3671 to us, that they ought not be changing the law unilaterally,
3672 and that they ought to be exercising the constitutional
3673 prerogative of bringing their suggestions and their
3674 recommendations to the United States Congress.

3675 So on that side, I agree with many of the comments of my
3676 colleagues on this side of the aisle. On the other side, I
3677 represent a fairly rural district, and while it may be
3678 lowering the price somewhat to have the preferred network, if
3679 the preferred network, the chain pharmacy, is located 20
3680 miles away and around the other side of the mountain, I have

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3681 people who aren't being adequately served by this program.

3682 And so, gentlemen, I ask you, how do we solve that
3683 problem? How do we solve the problem where we may be getting
3684 the price down, but we are making it very, very difficult for
3685 my constituents to get to see the pharmacist who is
3686 prescribing their drug, and who--and, you know, in these
3687 rural areas, particularly a rural, mountainous area where
3688 they may not have but one pharmacy, and if that pharmacy is
3689 not in that particular town, part of this preferred network,
3690 and they have to go to the next town over, it may be a good
3691 distance. And particularly when most of these folks may not
3692 really like getting out driving, particularly, as we have had
3693 this winter, a fair amount of snow. How do you solve that
3694 problem? And I don't mind putting a Bill in if that is what
3695 you think we need to do, but I do think that, Dr. Holtz-
3696 Eakin, it may impact the pricing somewhat, but there is a big
3697 difference between walking down the block in New York City
3698 and getting from Haysi to Clintwood.

3699 Mr. {Holtz-Eakin.} I agree with that completely, and I
3700 am not familiar with your district so I won't pretend too
3701 much knowledge, but we won't have to solve all problems with
3702 the same provisions. And the overall goal of this should be

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3703 to get prescription drug coverage at as low cost possible for
3704 beneficiaries. I mean that is a key feature of the design.

3705 Now, which vender delivers that, I don't think we should
3706 have a stake in. Perhaps mail-order is better for some of
3707 your folks as opposed to traveling at all. Have it delivered
3708 to their home. We need to make sure that we have a system
3709 that allows the negotiations to be as intense as possible
3710 with the manufacturers to get prices down, and then use a
3711 variety of delivery mechanisms to get them to seniors. And I
3712 think that should be the overall objective. No question.

3713 We should trust the seniors to figure it out.

3714 Mr. {Griffith.} Well, of course the problem with--in
3715 all fairness, with mail-order is if you have questions or if
3716 you have had a, you know, a little rash that might have been
3717 caused by that, your pharmacist is in a far better position
3718 than your UPS or mail deliverer to--

3719 Mr. {Holtz-Eakin.} Okay.

3720 Mr. {Griffith.} --explain to you that, well, that is
3721 actually one of the side-effects buried way down in the notes
3722 I have here.

3723 Mr. {Holtz-Eakin.} I would concur, and I--

3724 Mr. {Griffith.} And so that is another problem that I

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3725 have.

3726 Mr. {Holtz-Eakin.} --almost never have a--discussion.

3727 But I guess the second thing I would say is not all

3728 competition is on prices. We do want low prices, but there

3729 are many services associated, you know, advice about

3730 prescriptions, people are worried about seniors being in the

3731 right plan, well, you know, we trust people to make choices

3732 right up to the age of 64 on the exchanges, and 65 suddenly

3733 they are incapable? I think they can probably figure it out,

3734 but if they can't, they can talk to their pharmacist, am I in

3735 the right plan, this what I typically have. You know, there

3736 are some other aspects--

3737 Mr. {Griffith.} I am running out of time.

3738 Mr. {Holtz-Eakin.} --that could be--

3739 Mr. {Griffith.} I do want to give Mr. Baker an

3740 opportunity to resolve the dilemma, and you may want to touch

3741 on how the CMS has the legal authority to go forward with

3742 what they are doing, even though I agree with you on the any

3743 willing Provider portions.

3744 Mr. {Baker.} I think that 2 things. One is that,

3745 certainly, there are--there is a balancing here, and the

3746 example that we have in our testimony was a \$300 difference.

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3747 So I mean I don't think the service, you know, component
3748 makes--allows that person to afford the \$300 at the local
3749 community pharmacy. So I think, once again, the any willing
3750 Provider is a, I think, a moderate solution. I mean I think
3751 for 2 reasons I am the wrong person to ask about the
3752 interference piece, one, because I am not--I am a lawyer but
3753 I am not, I don't think qualified to do this constitutional
3754 interpretation, and--

3755 Mr. {Griffith.} But you do agree there is a difference
3756 between and and or.

3757 Mr. {Baker.} I would agree--

3758 Mr. {Griffith.} As a lawyer, you know there is.

3759 Mr. {Baker.} --with that.

3760 Mr. {Griffith.} Yes.

3761 Mr. {Baker.} I will agree with that.

3762 Mr. {Griffith.} Yes. Absolutely. And so that is my
3763 concern. And I hate to cut you off because I am running out
3764 of time.

3765 Mr. {Baker.} Sure.

3766 Mr. {Griffith.} I have other concerns about both the
3767 rule and the fact that, you know, maybe it is time for us to
3768 take a look at some of the things that may be working to a

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3769 disadvantage. I have another letter here from one of my
3770 pharmacists who is in a specialized area, and they can't even
3771 figure out what they are going to get paid until after they
3772 have already provided the drug because of the way the system
3773 is set up, but that--I will have to deal with that another
3774 time because my time is out.

3775 I do appreciate it. I have been--this hearing--totally,
3776 Mr. Chairman, I have been educated even more on this subject
3777 matter, and do appreciate it, and that is why we have these
3778 discussions and it is good to have.

3779 Thank you, sir, and I yield back.

3780 Mr. {Pitts.} Chair thanks the gentleman, and we will
3781 provide questions to you, if you will please respond in
3782 writing promptly.

3783 I remind members that they have 10 business days to
3784 submit questions for the record. And I ask witnesses to
3785 respond promptly. And members should submit their questions
3786 by the close of business on Wednesday, March 12.

3787 Dr. Burgess, you have a unanimous consent request?

3788 Dr. {Burgess.} Yes, Mr. Chairman. I have an opinion
3789 piece from June of 2012 that almost prophetically foretold
3790 the problems that would be visited upon the Part D Program by

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3791 the Affordable Care Act, and I would like to submit that for
3792 the record. It was a very insightful piece that was written.

3793 Mr. {Pitts.} Without objection, so ordered.

3794 [The information follows:]

3795 ***** COMMITTEE INSERT *****

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3796 Mr. {Pitts.} This has been a very informative hearing,
3797 very important issue. Thank you very much for your--
3798 {Voice.} Thank you.
3799 Mr. {Pitts.} --patience.
3800 Without objection, the subcommittee is adjourned.
3801 [Whereupon, at 1:25 p.m., the Subcommittee was
3802 adjourned.]